

FLUID-ASSISTED MEDICAL DEVICES, SYSTEMS AND METHODS

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the name of TissueLink Medical, Inc. (a U.S. national corporation), for the
5 designation of all countries except the U.S., and Michael E. McClurken, David
Lipson, David Flanagan and Scott D. O'Brien (all U.S. citizens), for the designation
of the US only, on 27 March 2003.

Field

10 This invention relates generally to the field of medical devices and methods
for use upon a body during surgery. More particularly, the invention relates to
electrosurgical devices, systems and methods for use upon tissues of a human body
during surgery, particularly open surgery and minimally invasive surgery such as
laparoscopic surgery.

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Background

Electrosurgical devices configured for use with a dry tip use electrical energy,
often radio frequency (RF) energy, to cut tissue or to cauterize blood vessels.
During use, a voltage gradient is created at the tip of the device, thereby inducing
20 current flow and related heat generation in the tissue. With sufficiently high levels
of electrical power, the heat generated is sufficient to cut the tissue and,
advantageously, to stop the bleeding from severed blood vessels.

Current dry tip electrosurgical devices can cause the temperature of tissue
being treated to rise significantly higher than 100 °C, resulting in tissue desiccation,
25 tissue sticking to the electrodes, tissue perforation, char formation and smoke
generation. Desiccation occurs when tissue temperature exceeds 100 °C and all of
the intracellular water boils away, leaving the tissue extremely dry and much less
electrically conductive. Peak temperatures of target tissue as a result of dry RF
treatment can be as high as 320 °C, and such high temperatures can be transmitted to
30 adjacent tissue via thermal diffusion. Consequently, this may result in undesirable
desiccation and thermal damage to the adjacent tissue.

The use of saline inhibits undesirable effects such as tissue desiccation,
electrode sticking, smoke production and char formation. However, an uncontrolled
or abundant flow rate of saline can provide too much electrical dispersion and
35 cooling at the electrode/tissue interface. This reduces the temperature of the target
tissue being treated, and, in turn, can result in longer treatment time to achieve the
desired tissue temperature for treatment of the tissue. Long treatment times are

undesirable for surgeons since it is in the best interest of the patient, physician and hospital, to perform surgical procedures as quickly as possible.

RF power delivered to tissue can be less than optimal when using general-purpose generators. Most general-purpose RF generators have modes for different waveforms (e.g., cut, coagulation, or blend) and device types (e.g., monopolar, bipolar), as well as power levels that can be set in watts. However, once these settings are chosen, the actual power delivered to tissue and associated heat generated can vary dramatically over time as tissue impedance changes during the course of RF treatment. This is because the power delivered by most generators is a function of tissue impedance, with the power ramping down as impedance either decreases toward zero or increases significantly to several thousand ohms. Current dry tip electrosurgical devices are not configured to address a change in power provided by the generator as tissue impedance changes or the associated effect on tissue, and rely on the surgeon's expertise to overcome this limitation.

The patent application is related to United States provisional application serial no. _____, filed March 6, 2003 (having attorney docket number 13045.40USP1) and also to United States provisional application serial number 60/368,177, filed March 27, 2002, now pending.

This patent application is also related to United States patent application serial no. 09/947,658, filed September 5, 2001, now pending, which is a continuation-in-part of United States patent application serial no. 09/797,049, filed March 1, 2001, now pending, which claimed priority to United States provisional application serial no. 60/187,114, filed March 6, 2000.

This patent application is also related to United States patent application serial no. 09/668,403, filed September 22, 2000, now pending.

This patent application is also related to PCT patent application serial no. PCT/US02/28488, filed September 6, 2002, now pending.

The entire disclosure of each of these patent applications is incorporated herein by reference to the extent it is consistent.

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Summary of the Invention

The invention is directed to various embodiments of electrosurgical devices, systems and methods. In one preferred embodiment, an electrosurgical device has a handle, a shaft extending from the handle having a distal end, and an electrode tip having an electrode surface with at least a portion of the electrode tip extending distally beyond the distal end of the shaft. In one embodiment, preferably the portion of the electrode tip extending distally beyond the distal end of the shaft comprises a cone shaped portion. The device also has a fluid passage being

connectable to a fluid source and at least one fluid outlet opening in fluid communication with the fluid passage.

In another preferred embodiment, the electrode tip extending distally beyond the distal end of the shaft has a neck portion and an enlarged end portion with the 5 enlarged end portion located distal to the neck portion and comprising the cone shaped portion.

In another preferred embodiment, the fluid outlet opening is arranged to provide a fluid from the fluid source to the neck portion of the electrode tip.

In yet another preferred embodiment, the fluid outlet opening is arranged to 10 provide a fluid from the fluid source towards the enlarged end portion of the electrode tip.

In another preferred embodiment, an electrosurgical device has a handle, and an electrode tip having an electrode surface with the electrode surface and comprising a cone shaped portion. The device also has a fluid passage being 15 connectable to a fluid source and at least one fluid outlet opening in fluid communication with the fluid passage and arranged to provide a fluid from the fluid source to the cone shaped portion of the electrode tip.

The invention is also directed to a surgical method for treating tissue. The method includes providing tissue having a tissue surface, providing radio frequency power at a power level, providing an electrically conductive fluid at a fluid flow 20 rate, providing an surgical device configured to simultaneously provide the radio frequency electrical power and the electrically conductive fluid to tissue, providing the electrically conductive fluid to the tissue at the tissue surface, forming a fluid coupling comprising the electrically conductive fluid which couples the tissue and 25 the surgical device, providing the radio frequency power to the tissue at the tissue surface and below the tissue surface into the tissue through the fluid coupling, coagulating the tissue without cutting the tissue, and dissecting the tissue after coagulating the tissue. Preferably, the device comprises an electrode tip having an electrode surface, and comprising a cone shaped portion and a distal end. Also 30 preferably, coagulating the tissue is performed with the cone shaped portion and dissecting is performed with the distal end of the device. In various embodiments, the dissection may be blunt as where the distal end of the device is blunt, or sharp as where the distal end of the device is pointed.

The invention is also directed to various embodiments of an adaptor for 35 electrically coupling between an electrosurgical generator and a bipolar electrosurgical device. In one preferred embodiment, the adaptor comprises a power input connector for coupling the adaptor with a monopolar mode power output connector of the electrosurgical generator, a ground connector for coupling the

adaptor with a ground connector of the electrosurgical generator, a first and a second power output connector, each for coupling the adaptor with a first and a second bipolar mode power input connector of the bipolar electrosurgical device, respectively, a transformer coupled between the power input connector and the first and second power output connectors, a monopolar hand switch connector for coupling the adaptor with a monopolar mode hand switch connector of the electrosurgical generator, and at least one bipolar mode hand switch connector for coupling the adaptor with a bipolar mode hand switch connector of the electrosurgical device.

The invention is also directed to various embodiments of a bipolar electrosurgical device. In one preferred embodiment, the device comprises a first electrode tip and a second electrode tip with the electrode tips coupled to an impedance transformer provided with the electrosurgical device, at least one fluid delivery passage being connectable to a fluid source, at least one fluid outlet opening in fluid communication with the at least one fluid delivery passage, the electrode tips configured to paint along a tissue surface in the presence of fluid from the fluid outlet opening as the tips are moved along the tissue surface whereby the tissue surface can be coagulated without cutting upon the application of radio frequency energy from the electrodes simultaneously with fluid from the fluid outlet opening while the tips are coupled with the fluid adjacent the tissue surface and moved along the tissue surface.

The invention is also directed to various embodiments of medical kits. In one preferred embodiment, the kit has an electrosurgical device configured to provide radio frequency power and a fluid to a tissue treatment site, and a transformer. In various embodiments, the electrosurgical device and transformer may be provided as separate connectable components, or integrally as a single piece.

Brief Description Of The Drawings

FIG. 1 is a block diagram showing one embodiment of a control system of the invention, and an electrosurgical device;

FIG. 2 is a schematic graph that describes a relationship between RF power to tissue (P , in watts), flow rate of saline (Q , in cc/sec.), and tissue temperature (T , in °C) when heat conduction to adjacent tissue is considered;

FIG. 3 is schematic graph that describes a relationship between RF power to tissue (P , in watts), flow rate of saline (Q , in cc/sec.), and tissue temperature (T , in °C) when heat conduction to adjacent tissue is neglected;

FIG. 4 is a schematic graph that describes a relationship between RF power to tissue (P , in watts), flow rate of saline (Q , in cc/sec.), and tissue temperature (T , in

°C) when the heat required to warm the tissue to the peak temperature (T) is considered;

FIG. 5 is a graph that describes a relationship between percentage saline boiling (%) and saline flow rate (Q, in cc/min) for an exemplary RF generator output setting of 75 watts;

FIG. 6 is a schematic graph that describes a relationship between load impedance (Z, in ohms) and generator output power (P, in watts), for an exemplary RF generator output setting of 75 watts in a bipolar mode;

FIG. 7 is a schematic graph that describes a relationship between time (t, in seconds) and tissue impedance (Z, in ohms) after RF activation;

FIG. 8 is a schematic perspective view of a cannula which may be used with an electrosurgical device according to the present invention;

FIG. 9 is a schematic exploded perspective view of an assembly of an electrosurgical device according to the present invention;

FIG. 10 is a schematic longitudinal cross-sectional side view of the tip and shaft of the device of FIG. 9 taken along line 10-10 of FIG. 12;

FIG. 11 is a schematic close-up longitudinal cross-sectional side view of the tip portion of the device bounded by circle 45 shown in FIG. 10 taken along line 10-10 of FIG. 12;

FIG. 12 is a schematic distal end view of the tip portion of the device bounded by circle 45 shown in FIG. 10;

FIG. 13 is a schematic side view of the tip and shaft of the device of FIG. 9 with a fluid coupling to a tissue surface of tissue;

FIG. 14 is a schematic close-up side view of an alternative tip portion;

FIG. 15 is a schematic close-up cross-sectional side view of the tip portion of FIG. 14 taken along line 15-15 of FIG. 14;

FIG. 16 is a schematic close-up cross-sectional side view of the tip portion of FIG. 14 disposed in a tissue crevice;

FIG. 17 is a schematic graph that describes a relationship between time (t, in seconds) and changes in impedance (Z, in ohms) represented by impedance spikes;

FIG. 18 is a schematic graph that describes a relationship between percentage saline boiling (%) and impedance (Z, in ohms);

FIG. 19 is schematic close-up cross-sectional view of a sleeve taken along line 19-19 of FIG. 15;

FIG. 20 is a schematic close-up perspective view of an alternative tip portion;

FIG. 21 is a schematic close-up cross-sectional side view of the tip portion of FIG. 20 taken along line 21-21 of FIG. 20;

FIG. 22 is a schematic close-up cross-sectional side view of the tip portion of FIG. 20 disposed in a tissue crevice;

FIG. 23 is a schematic close-up front perspective view of the electrode for the tip portion of FIG. 20;

5 FIG. 24 is a schematic close-up rear perspective view of the electrode for the tip portion of FIG. 20;

FIG. 25 is a schematic close up cross-sectional view of a porous electrode with recesses;

10 FIG. 26 is schematic close up cross-sectional view of an electrode with semi-circular recesses;

FIG. 27 is schematic close up cross-sectional view of an electrode with V-shaped recesses;

FIG. 28 is schematic close up cross-sectional view of an electrode with U-shaped recesses;

15 FIG. 29 is a schematic close-up perspective view of an alternative tip portion;

FIG. 30 is a schematic close-up cross-sectional side view of the tip portion of FIG. 29 taken along line 30-30 of FIG. 29;

20 FIG. 31 is a schematic close-up perspective view of an alternative tip portion;

FIG. 32 is a schematic close-up cross-sectional side view of the tip portion of FIG. 31 taken along line 32-32 of FIG. 31;

FIG. 33 is a schematic close-up perspective view of an alternative tip portion;

25 FIG. 34 is a schematic close-up cross-sectional side view of the tip portion of FIG. 33 taken along line 34-34 of FIG. 33;

FIG. 35 is a schematic close-up perspective view of an alternative tip portion;

30 FIG. 36 is a schematic close-up cross-sectional side view of the tip portion of FIG. 35 taken along line 36-36 of FIG. 35;

FIG. 37 is a schematic close up side view of an alternative cone shape portion of an electrode;

FIG. 38 is a schematic close up side view of an alternative cone shape portion of an electrode;

35 FIG. 39 is a schematic close up side view of an alternative cone shape portion of an electrode;

FIG. 40 is a schematic close up side view of an alternative cone shape portion of an electrode;

FIG. 41 is a schematic exploded perspective view of an assembly of an alternative electrosurgical device according to the present invention;

FIG. 42 is a schematic close-up cross-sectional side view of the tip portions of FIG. 41 assembled with a fluid coupling to a tissue surface of tissue;

5 FIG. 43 is a schematic close-up cross-sectional side view of the tip portions of FIG. 41 assembled with an alternative fluid coupling to a tissue surface of tissue;

FIG. 44 is a block diagram showing another embodiment of a control system of the invention, and an electrosurgical device;

10 FIG. 45 is a block diagram of an electrical configuration for a generator and a bipolar device without a hand switch;

FIG. 46 is a block diagram of an electrical configuration for a generator and a monopolar device with a hand switch;

15 FIG. 47 is a block diagram of an electrical configuration for a generator and a bipolar device with a hand switch and a transformer;

FIG. 48 is a block diagram of an electrical configuration for a generator and a bipolar device without a handswitch and with a transformer;

20 FIG. 49 is a block diagram of an electrical configuration for a generator, a bipolar device without a hand switch, and an adaptor with a transformer therebetween;

FIG. 50 is a block diagram of an electrical configuration for a generator and a bipolar device with a hand switch;

25 FIG. 51 is a block diagram of an electrical configuration for a generator, a bipolar device with a hand switch, and an adaptor with a transformer therebetween;

FIG. 52 is a schematic perspective view of an alternative electrosurgical device according to the present invention;

30 FIG. 53 is a schematic perspective view of a handle portion of the device of FIG. 52 assembled with various components;

FIG. 54 is a schematic side view of a handle portion of the device of FIG. 52 assembled with various components;

35 FIG. 55 is a schematic side view of a handle portion of the device of FIG. 52 assembled with various components;

FIG. 56 is a schematic side view of a handle portion of the device of FIG. 52 assembled with various components;

FIG. 57 is a schematic perspective view of an alternative electrosurgical device according to the present invention;

40 FIG. 58 is a schematic perspective view of a handle portion of the device of FIG. 57 assembled with various components; and

FIG. 59 is a schematic side view of a handle portion of the device of FIG. 52 assembled with various components.

Detailed Description

Throughout the description, like reference numerals and letters indicate corresponding structure throughout the several views, and such corresponding structure need not be separately discussed. Furthermore, any particular feature(s) of a particular exemplary embodiment may be equally applied to any other exemplary embodiment(s) of this specification as suitable. In other words, features between the various exemplary embodiments described herein are interchangeable as suitable, and not exclusive.

The invention provides devices, systems and methods that control tissue temperature at a tissue treatment site during a medical procedure. This is particularly useful during surgical procedures upon tissues of the body, where it is desirable to seal, coagulate and shrink tissue, to occlude lumens of blood vessels (e.g., arteries, veins), airways (e.g., bronchi, bronchioles), bile ducts and lymphatic ducts.

The invention includes electrosurgical procedures, which preferably utilize RF power and electrically conductive fluid, to treat tissue. Preferably, a desired tissue temperature range is achieved by adjusting parameters, such as fluid flow rate, to affect the temperature at the tissue/electrode interface.

In one embodiment, the invention provides a control device, the device comprising a flow rate controller that receives a signal indicating power applied to the system, and adjusts the flow rate of fluid from a fluid source to the electrosurgical device. The invention also provides a control system comprising a flow rate controller, a measurement device that measures power applied to the system, and a pump that provides fluid at a selected flow rate.

The invention will be discussed generally with reference to FIG. 1, which shows a block diagram of one exemplary embodiment of a system of the invention. Preferably, an electrically conductive fluid 24 is provided from a fluid source 1 through a fluid line 2 to a pump 3, which has an outlet fluid line 4a that is connected as an input fluid line 4b to electrosurgical device 5. In a preferred embodiment, outlet fluid line 4a and input fluid line 4b are flexible and are made from a polymeric material, such as polyvinylchloride (PVC) or polyolefin (e.g., polypropylene, polyethylene) and the conductive fluid comprises a saline solution. More preferably, the saline comprises sterile, and even more preferably, normal saline. Although the description herein will specifically describe the use of saline as

the fluid 24, other electrically conductive fluids, as well as non-conductive fluids, can be used in accordance with the invention.

For example, in addition to the conductive fluid comprising physiologic saline (also known as "normal" saline, isotonic saline or 0.9% sodium chloride (NaCl) solution), the conductive fluid may comprise hypertonic saline solution, hypotonic saline solution, Ringers solution (a physiologic solution of distilled water containing specified amounts of sodium chloride, calcium chloride, and potassium chloride), lactated Ringer's solution (a crystalloid electrolyte sterile solution of distilled water containing specified amounts of calcium chloride, potassium chloride, sodium chloride, and sodium lactate), Locke-Ringer's solution (a buffered isotonic solution of distilled water containing specified amounts of sodium chloride, potassium chloride, calcium chloride, sodium bicarbonate, magnesium chloride, and dextrose), or any other electrolyte solution.

While a conductive fluid is preferred, as will become more apparent with further reading of this specification, fluid 24 may also comprise an electrically non-conductive fluid. The use of a non-conductive fluid is less preferred than a conductive fluid, however, the use of a non-conductive fluid still provides certain advantages over the use of a dry electrode including, for example, reduced occurrence of tissue sticking to the electrode of device 5 and cooling of the electrode and/or tissue. Therefore, it is also within the scope of the invention to include the use of a non-conducting fluid, such as, for example, deionized water.

Returning to FIG. 1, energy to heat tissue is provided from an energy source, such as an electrical generator 6 which preferably provides RF alternating current via a cable 7 to an energy source output measurement device, such as a power measurement device 8 that measures the RF alternating current electrical power. In one exemplary embodiment, preferably the power measurement device 8 does not turn the power off or on, or alter the power in any way. A power switch 15 connected to generator 6 is preferably provided by the generator manufacturer and is used to turn generator 6 on and off. The power switch 15 can comprise any switch to turn the power on and off, and is commonly provided in the form of a footswitch or other easily operated switch, such as a switch 15a mounted on electrosurgical device 5. The power switch 15 or 15a may also function as a manually activated device for increasing or decreasing the power provided from device 5.

Alternatively, internal circuitry and other components of generator 6 may be used for automatically increasing or decreasing the power provided from device 5. A cable 9 preferably provides RF power from power measurement device 8 to electrosurgical device 5. Power, or any other energy source output, is preferably measured before it reaches electrosurgical device 5.

When capacitance and induction effects are negligibly small, from Ohm's law, power P , or the rate of energy delivery (e.g., joules/sec), may be expressed by the product of current times voltage (i.e., $I \times V$), the current squared times resistance (i.e., $I^2 \times R$), or the voltage squared divided by the resistance (i.e., V^2/R); where the current I may be measured in amperes, the voltage V may be measured in volts, the electrical resistance R may be measured in ohms, and the power P may be measured in watts (joules/sec). Given that power P is a function of current I , voltage V , and resistance R as indicated above, it should be understood, that a change in power P is reflective of a change in at least one of the input variables. Thus, one may alternatively measure changes in such input variables themselves, rather than power P directly, with such changes in the input variables mathematically corresponding to a change in power P as indicated above.

Heating of the tissue is preferably performed by electrical resistance heating. That is, the temperature of the tissue increases as a result of electric current flow through the tissue, with the electrical energy being absorbed from the voltage and transformed into thermal energy (i.e., heat) via accelerated movement of ions as a function of the tissue's electrical resistance.

Referring again to FIG. 1, a flow rate controller 11 preferably includes a selection switch 12 that can be set to achieve desired levels of percentage fluid boiling (for example, 100%, 98%, 80% boiling). Preferably, flow rate controller 11 receives an input signal 10 from power measurement device 8 and calculates an appropriate mathematically predetermined fluid flow rate based on percentage boiling indicated by the selection switch 12. In a preferred embodiment, a fluid switch 13 is provided so that the fluid system can be primed (e.g., air eliminated) before turning on generator 6. The output signal 16 of flow rate controller 11 is preferably sent to pump 3 motor to regulate the flow rate of fluid, and thereby provide an appropriate fluid flow rate which corresponds to the amount of power being delivered.

In one embodiment, flow rate controller 11 is configured and arranged to be connected to a source of RF power (e.g., generator 6), and a source of fluid (e.g., fluid source 1), for example, a source of conductive fluid. The device of the invention receives information about the level of RF power applied to electrosurgical device 5, and adjusts the flow rate of fluid 24 to electrosurgical device 5, thereby controlling temperature at the tissue treatment site.

In another embodiment, elements of the system are physically included together in one electronic enclosure. One such embodiment is shown by enclosure within the outline box 14 of FIG 1. In the illustrated embodiment, pump 3, flow rate controller 11, and power measurement device 8 are enclosed within an enclosure,

and these elements are connected through electrical connections to allow signal 10 to pass from power measurement device 8 to flow rate controller 11, and signal 16 to pass from flow rate controller 11 to pump 3. Other elements of a system can also be included within one enclosure, depending upon such factors as the desired application of the system, and the requirements of the user.

Pump 3 can be any suitable pump to provide saline or other fluid at a desired flow rate. Preferably, pump 3 is a peristaltic pump. With a rotary peristaltic pump, typically a fluid 24 is conveyed within the confines of a flexible tube (e.g., 4a) by waves of contraction placed externally on the tube which are produced mechanically, typically by rotating rollers which intermittently squeeze the flexible tubing against a support with a linear peristaltic pump, typically a fluid 24 is conveyed within the confines of a flexible tube by waves of contraction placed externally on the tube which are produced mechanically, typically by a series of compression fingers or pads which sequentially squeeze the flexible tubing against a support. Peristaltic pumps are generally preferred, as the electro-mechanical force mechanism (e.g., rollers driven by electric motor) does not make contact the fluid 24, thus reducing the likelihood of inadvertent contamination.

Similar pumps can be used in connection with the invention, and the illustrated embodiments are exemplary only. The precise configuration of pump 3 is not critical to the invention. For example, pump 3 may include other types of infusion and withdrawal pumps. Furthermore, pump 3 may comprise pumps which may be categorized as syringe pumps, piston pumps, rotary vane pumps (e.g., axial impeller, centrifugal impeller), cartridge pumps and diaphragm pumps. In some embodiments, pump 3 can be substituted with any type of flow controller, such as a manual roller clamp used in conjunction with an IV bag, or combined with the flow controller to allow the user to control the flow rate of conductive fluid to the device. Alternatively, a valve configuration can be substituted for pump 3.

Fluid 24, such as conductive fluid, is preferably provided from an intravenous (IV) bag full of saline (e.g., fluid source 1) that flows by gravity. Fluid 24 may flow directly to electrosurgical device 5, or first to pump 3 located there between. Alternatively, fluid 24 from a fluid source 1 such as an IV bag can be provided through an IV flow controller that may provide a desired flow rate by adjusting the cross sectional area of a flow orifice (e.g., lumen of the connective tubing with the electrosurgical device 5) while sensing the flow rate with a sensor such as an optical drop counter. Furthermore, fluid 24 from a fluid source 1 such as an IV bag can be provided through a manually or automatically activated device such as a flow controller, such as a roller clamp, which also adjusts the cross sectional area of a flow orifice and may be adjusted manually by, for example, the

user of the device in response to their visual observation (e.g., fluid boiling) at the tissue treatment site or a pump.

Similar configurations of the system can be used in connection with the invention, and the illustrated embodiments are exemplary only. For example, the 5 fluid source 1, pump 3, generator 6, power measurement device 8 or flow rate controller 11, or any other components of the system not expressly recited above, may be present as a part of the electrosurgical device 5. For example, fluid source 1 may be a compartment of the electrosurgical device 5 which contains fluid 24, as indicated at reference character 1a. In another exemplary embodiment, the 10 compartment may be detachably connected to electrosurgical device 5, such as a canister which may be attached via threaded engagement with device 5. In yet another embodiment, the compartment may be configured to hold a pre-filled cartridge of fluid 24, rather than the fluid directly.

Also for example, with regards to alternatives for the generator 6, an energy 15 source, such as a direct current (DC) battery used in conjunction with inverter circuitry and a transformer to produce alternating current at a particular frequency, may comprise a portion of the electrosurgical device 5, as indicated at reference character 6a. In one embodiment the battery element of the energy source may comprise a rechargeable battery. In yet another exemplary embodiment, the battery 20 element may be detachably connected to the electrosurgical device 5, such as for recharging.

Use of the components of the system will now be described in further detail. From the specification, it should be clear that any use of the terms "distal" and "proximal" are made in reference from the user of the device, and not the patient.

25 Flow rate controller 11 controls the rate of flow from the fluid source 1. Preferably, the rate of fluid flow from fluid source 1 is based upon the amount of RF power provided from generator 6 to electrosurgical device 5. Referring to FIG. 2, there is illustrated a relationship between the rate of fluid flow Q and the RF power P. More precisely, as shown in FIG. 2, the relationship between the rate of fluid 30 flow Q and RF power P may be expressed as a direct, linear relationship. The flow rate Q of conductive fluid 24, such as saline, interacts with the RF power P and various modes of heat transfer to transfer heat away from the target tissue, as described herein.

Throughout this disclosure, when the terms "boiling point of saline", "vaporization point of saline", and variations thereof are used, what is actually 35 referenced for explanation purposes, is the boiling point of the water (i.e., 100°C) in the saline solution given that the difference between the boiling point of normal saline (about 100.16°C) and the boiling point of water is negligible.

FIG. 2 shows the relationship between the flow rate of saline, RF power to tissue, and regimes of boiling as detailed below. Based on a simple, one-dimensional, lumped parameter model of the heat transfer, the peak tissue temperature can be estimated, and once tissue temperature is estimated, it follows directly whether it is hot enough to boil saline. The total RF electrical power P that is converted into heat can be defined as:

$$P = \Delta T/R + \rho c_p Q_l \Delta T + \rho Q_b h_v \quad (1)$$

where P = the total RF electrical power that is converted into heat.

Conduction. The first term [$\Delta T/R$] in equation (1) is heat conducted to adjacent tissue, represented as 70 in FIG. 2, where:

$\Delta T = (T - T_\infty)$ the difference in temperature ($^{\circ}\text{C}$) between the peak tissue temperature (T) and the normal temperature (T_∞) of the body tissue; normal temperature of the body tissue is generally $37\text{ }^{\circ}\text{C}$; and

R = Thermal resistance of surrounding tissue, the ratio of the temperature difference to the heat flow ($^{\circ}\text{C}/\text{watt}$).

This thermal resistance can be estimated from published data gathered in experiments on human tissue (see for example, Phipps, J.H., "Thermometry studies with bipolar diathermy during hysterectomy," *Gynaecological Endoscopy*, 3:5-7 (1994)). As described by Phipps, Kleppinger bipolar forceps were used with an RF power of 50 watts, and the peak tissue temperature reached $320\text{ }^{\circ}\text{C}$. For example, using the energy balance of equation (1), and assuming all the RF heat put into tissue is conducted away, then R can be estimated:

$$R = \Delta T/P = (320-37)/50 = 5.7 \approx 6\text{ }^{\circ}\text{C}/\text{watt}$$

However, it is undesirable to allow the tissue temperature to reach $320\text{ }^{\circ}\text{C}$, since tissue will become desiccated. At a temperature of $320\text{ }^{\circ}\text{C}$, the fluid contained in the tissue is typically boiled away, resulting in the undesirable tissue effects described herein. Rather, it is preferred to keep the peak tissue temperature at no more than about $100\text{ }^{\circ}\text{C}$ to inhibit desiccation of the tissue. Assuming that saline boils at about $100\text{ }^{\circ}\text{C}$, the first term in equation (1) ($\Delta T/R$) is equal to $(100 - 37)/6 =$

10.5 watts. Thus, based on this example, the maximum amount of heat conducted to adjacent tissue without any significant risk of tissue desiccation is 10.5 watts.

Referring again to FIG. 2, RF power to tissue is represented on the X-axis as P (watts) and flow rate of saline (cc/min) is represented on the Y-axis as Q. When 5 the flow rate of saline equals zero ($Q = 0$), there is an "offset" RF power that shifts the origin of the sloped lines 76, 78, and 80 to the right. This offset is the heat conducted to adjacent tissue. For example, using the calculation above for bipolar forceps, this offset RF power is about 10.5 watts. If the power is increased above this level with no saline flow, the peak tissue temperature can rise well above 100 10 °C, resulting in tissue desiccation from the boiling off of water in the cells of the tissue.

Convection. The second term [$\rho c_p Q_l \Delta T$] in equation (1) is heat used to warm up the saline without boiling the saline, represented as 72 in FIG. 2, where:

15 ρ = Density of the saline fluid that gets hot but does not boil (approximately 1.0 gm/cm³);
 c_p = Specific heat of the saline (approximately 4.1 watt-sec/gm-°C);
 Q_l = Flow rate of the saline that is heated (cm³/sec); and
 ΔT = Temperature rise of the saline. Assuming that the saline is heated to 20 body temperature before it reaches the electrode, and that the peak saline temperature is similar to the peak tissue temperature, this is the same ΔT as for the conduction calculation above.

The onset of boiling can be predicted using equation (1) with the last term on 25 the right set to zero (no boiling), i.e. $\rho Q_b h_v = 0$, and solving equation (1) for Q_l leads to:

$$Q_l = [P - \Delta T/R]/\rho c_p \Delta T \quad (2)$$

30 This equation defines the line shown in FIG. 2 as the line of onset of boiling 76.

Boiling. The third term [$\rho Q_b h_v$] in equation (1) relates to heat that goes into converting the water in liquid saline to water vapor, and is represented as 74 in FIG. 35 2, where:

Q_b = Flow rate of saline that boils (cm³/sec); and
 h_v = Heat of vaporization of saline (approximately 2,000 watt-sec/gm).

A flow rate of only 1 cc/min will absorb a significant amount of heat if it is completely boiled, or about $\rho Q_b h_v = (1) (1/60) (2,000) = 33.3$ watts. The heat needed to warm this flow rate from body temperature to 100 °C is much less, or $\rho c_p Q_l \Delta T = (1) (4.1) (1/60) (100 - 37) = 4.3$ watts. In other words, the most 5 significant factor contributing to heat transfer from a wet electrode device can be fractional boiling. The present invention recognizes this fact and exploits it.

Fractional boiling can be described by equation (3) below:

$$Q_l = \frac{\{P - \Delta T/R\}}{\{\rho c_p \Delta T + \rho h_v Q_b / Q_l\}} \quad (3)$$

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If the ratio of Q_b / Q_l is 0.50 this is the 50% boiling line 78 shown in FIG. 2. If the ratio is 1.0 this is the 100% boiling line 80 shown in FIG. 2.

As indicated previously in the specification, use of a fluid to couple energy to tissue inhibits undesirable effects such as tissue desiccation, electrode sticking, 15 char formation and smoke production. Tissue desiccation, which occurs if the tissue temperature exceeds 100 °C and all the intracellular water boils away, is particularly undesirable as it leaves the tissue extremely dry and much less electrically conductive.

As shown in FIG. 2, one control strategy or mechanism which can be 20 employed for the electrosurgical device 5 is to adjust the power P and flow rate Q such that the power P used at a corresponding flow rate Q is equal to or less than the power P required to boil 100% of the fluid, and does not exceed the power P required to boil 100% of the fluid. This control strategy targets using the electrosurgical device 5 in the regions of FIG. 2 identified as $T < 100$ °C and $T = 25 100$ °C, and includes the 100% boiling line 80. That is, this control strategy targets not using the electrosurgical device 5 only in the region of FIG. 2 identified as $T >> 100$ °C.

Another control strategy that can be used for the electrosurgical device 5 is to 30 operate device 5 in the region $T < 100$ °C, but at high enough temperature to shrink tissue containing Type I collagen (e.g., walls of blood vessels, bronchi, bile ducts, etc.), which shrinks when exposed to about 85 °C for an exposure time of 0.01 seconds, or when exposed to about 65 °C for an exposure time of 15 minutes. An exemplary target temperature/time for tissue shrinkage is about 75 °C with an exposure time of about 1 second. A determination of the high end of the scale (i.e., 35 when the fluid reaches 100 °C) can be made by the phase change in the fluid from liquid to vapor. However, a determination at the low end of the scale (e.g., when the fluid reaches, for example, 75 °C for 1 second) requires a different mechanism as the

temperature of the fluid is below the boiling temperature and no such phase change is apparent.

- In order to determine when the fluid reaches a temperature that will facilitate tissue shrinkage, for example 75 °C, a thermochromic material, such as a
5 thermochromic dye (e.g., leuco dye), may be added to the fluid. The dye can be formulated to provide a first predetermined color to the fluid at temperatures below a threshold temperature, such as 75 °C, then, upon heating above 75 °C, the dye provides a second color, such as clear, thus turning the fluid clear (i.e., no color or reduction in color). This color change may be gradual, incremental, or instant.
10 Thus, a change in the color of the fluid, from a first color to a second color (or lack thereof) provides a visual indication to the user of the electrosurgical device 5 as to when a threshold fluid temperature below boiling has been achieved.
Thermochromic dyes are available, for example, from Color Change Corporation,
1740 Cortland Court, Unit A, Addison, IL 60101.
15 It is also noted that the above mechanism (i.e., a change in the color of the fluid due to a dye) may also be used to detect when the fluid reaches a temperature which will facilitate tissue necrosis; this generally varies from about 60 °C for an exposure time of 0.01 seconds and decreasing to about 45 °C for an exposure time of 15 minutes. An exemplary target temperature/time for tissue necrosis is about 55 °C
20 for an exposure time of about 1 second.

In order to reduce time, use of the electrosurgical device 5 in the region $T = 100$ °C of FIG. 2 is preferable to use of the electrosurgical device 5 in the region $T < 100$ °C. Consequently, as shown in FIG. 2, another control strategy which may be employed for the electrosurgical device 5 is to adjust the power P and flow rate Q
25 such that the power P used at a corresponding flow rate Q is equal to or more than the power P required to initiate boiling of the fluid, but still less than the power P required to boil 100% of the fluid. This control strategy targets using the electrosurgical device 5 in the region of FIG. 2 identified as $T = 100$ °C, and includes the lines of the onset of boiling 76 and 100% boiling line 80. That is, this
30 control strategy targets using the electrosurgical device 5 on or between the lines of the onset of boiling 76 and 100% boiling line 80, and not using the electrosurgical device 5 in the regions of FIG. 2 identified as $T < 100$ °C and $T \gg 100$ °C.

For consistent tissue effect, it is desirable to control the saline flow rate so that it is always on a “line of constant % boiling” as, for example, the line of the
35 onset of boiling 76 or the 100% boiling line 80 or any line of constant % boiling located in between (e.g., 50% boiling line 78) as shown in FIG. 2. Consequently, another control strategy that can be used for the electrosurgical device 5 is to adjust

power P and flow rate Q such that the power P used at a corresponding flow rate Q targets a line of constant % boiling.

It should be noted, from the preceding equations, that the slope of any line of constant % boiling is known. For example, for the line of the onset of boiling 76, the slope of the line is given by $(\rho c_p \Delta T)$, while the slope of the 100% boiling line 80 is given by $1/(\rho c_p \Delta T + \rho h_v)$. As for the 50% boiling line 78, for example, the slope is given by $1/(\rho c_p \Delta T + \rho h_v 0.5)$.

If, upon application of the electrosurgical device 5 to the tissue, boiling of the fluid is not detected, such indicates that the temperature is less than 100 °C as shown by the area $T < 100$ °C of FIG. 2, and the flow rate Q must be decreased to initiate boiling if the power remains unchanged. The flow rate Q may be decreased until boiling of the fluid is first detected, at which time the line of the onset of boiling 76 is transgressed and the point of transgression on the line 76 is determined. From the determination of a point on the line of the onset of boiling 76 for a particular power P and flow rate Q , and the known slope of the line 76 as outlined above (i.e., $1/\rho c_p \Delta T$), it is also possible to determine the heat conducted to adjacent tissue 70.

Conversely, if upon application of the electrosurgical device 5 to the tissue, boiling of the fluid is detected, such indicates that the temperature is approximately equal to 100 °C as shown by the area $T = 100$ °C of FIG. 2, and the flow rate Q must be increased to reduce boiling until boiling stops, at which time the line of the onset of boiling 76 is transgressed and the point of transgression on the line 76 determined. As with above, from the determination of a point on the line of the onset of boiling 76 for a particular power P and flow rate Q , and the known slope of the line 76, it is also possible to determine the heat conducted to adjacent tissue 70.

With regards to the detection of boiling of the fluid, preferably such is physically detected by the user (e.g., visually by the naked eye) in the form of either bubbles or steam evolving from the fluid coupling at the electrode/tissue interface. Alternatively, such a phase change (i.e., from liquid to vapor or vice-versa) may be measured by a sensor which preferably senses either an absolute change (e.g., existence or non-existence of boiling with binary response such as yes or no) or a change in a physical quantity or intensity and converts the change into a useful input signal for an information-gathering system. For example, the phase change associated with the onset of boiling may be detected by a pressure sensor, such as a pressure transducer, located on the electrosurgical device 5. Alternatively, the phase change associated with the onset of boiling may be detected by a temperature sensor, such as a thermistor or thermocouple, located on the electrosurgical device 5, such as adjacent to the electrode. Also alternatively, the phase change associated with the

onset of boiling may be detected by a change in the electric properties of the fluid itself. For example, a change in the electrical resistance of the fluid may be detected by an ohm meter; a change in the amperage may be measured by an amp meter; a change in the voltage may be detected by a volt meter; and a change in the power 5 may be determined by a power meter.

Yet another control strategy which may be employed for the electrosurgical device 5 is to eliminate the heat conduction term 70 of equation (1) (i.e., $\Delta T/R$). Since the amount of heat conducted away to adjacent tissue can be difficult to precisely predict, as it may vary, for example, by tissue type, it may be preferable, 10 from a control point of view, to assume the worst case situation of zero heat conduction, and provide enough saline so that if necessary, all the RF power could be used to heat up and boil the saline, thus providing that the peak tissue temperature will not go over 100 °C significantly. This is shown in the schematic graph of FIG. 3.

15 Stated another way, if the heat conducted to adjacent tissue 70 is overestimated, the power P required to intersect the 100% boiling line 80 will, in turn, be overestimated and the 100% boiling line 80 will be transgressed into the $T >> 100$ °C region of FIG. 2, which is undesirable as established above. Thus, assuming the worse case situation of zero heat conduction provides a "safety factor" 20 to avoid transgressing the 100% boiling line 80. Assuming heat conduction to adjacent tissue 70 to be zero also provides the advantage of eliminating the only term from equation (1) which is tissue dependent, i.e., depends on tissue type. Thus, provided ρ , c_p , ΔT , and h_v are known as indicated above, the equation of the line for 25 any line of constant % boiling is known. Thus, for example, the 98% boiling line, 80% boiling line, etc. can be determined in response to a corresponding input from selection switch 12. In order to promote flexibility, it should be understood that the input from the selection switch preferably may comprise any percentage of boiling. Preferably the percentage of boiling can be selected in single percent increments 30 (i.e., 100%, 99%, 98%, etc.).

Upon determination of the line of the onset of boiling 76, the 100% boiling line 80 or any line of constant % boiling there between, it is generally desirable to control the flow rate Q so that it is always on a particular line of constant % boiling for consistent tissue effect. In such a situation, flow rate controller 11 will adjust the flow rate Q of the fluid 24 to reflect changes in power P provided by the generator 35 6, as discussed in greater detail below. For such a use flow rate controller 11 may be set in a line of constant boiling mode, upon which the % boiling is then correspondingly selected.

As indicated above, it is desirable to control the saline flow rate Q so that it is always on a line of constant % boiling for consistent tissue effect. However, the preferred line of constant % boiling may vary based on the type of electrosurgical device 5. For example, if with use of the device 5, shunting through saline is not an issue, then it can be preferable to operate close to or directly on, but not over the line of the onset of boiling, such as 76a in FIG. 3. This preferably keeps tissue as hot as possible without causing desiccation. Alternatively, if with use of the device 5 shunting of electrical energy through excess saline is an issue, then it can be preferable to operate along a line of constant boiling, such as line 78a in FIG. 3, the 10 50% line. This simple proportional control will have the flow rate determined by equation (4), where K is the proportionality constant:

$$Q_l = K \times P \quad (4)$$

In essence, when power P goes up, the flow rate Q will be proportionately increased. Conversely, when power P goes down, the flow rate Q will be proportionately decreased.

The proportionality constant K is primarily dependent on the fraction of saline that boils, as shown in equation (5), which is equation (3) solved for K after 20 eliminating P using equation (4), and neglecting the conduction term ($\Delta T/R$):

$$K = \frac{1}{\{\rho c_p \Delta T + \rho h_v Q_b / Q_l\}} \quad (5)$$

Thus, the present invention provides a method of controlling boiling of fluid, such as a conductive fluid, at the tissue/electrode interface. In a preferred embodiment, this provides a method of treating tissue without use of tissue sensors, such as temperature or impedance sensors. Preferably, the invention can control boiling of conductive fluid at the tissue/electrode interface and thereby control tissue temperature without the use of feedback loops.

In describing the control strategy of the present invention described thus far, focus has been drawn to a steady state condition. However, the heat required to warm the tissue to the peak temperature (T) may be incorporated into equation (1) as follows:

$$P = \Delta T/R + \rho c_p Q_l \Delta T + \rho Q_b h_v + \rho c_p V \Delta T / \Delta t \quad (6)$$

where $\rho c_p V \Delta T / \Delta t$ represents the heat required to warm the tissue to the peak temperature (T) 68 and where :

ρ = Density of the saline fluid that gets hot but does not boil (approximately 1.0 gm/cm³);

c_p = Specific heat of the saline (approximately 4.1 watt-sec/gm-°C);

V = Volume of treated tissue;

5 ΔT = ($T - T_\infty$) the difference in temperature (°C) between the peak tissue temperature (T) and the normal temperature (T_∞) of the body tissue; normal temperature of the body tissue is generally 37 °C; and

Δt = ($t - t_\infty$) the difference in time to achieve peak tissue temperature (T) and the normal temperature (T_∞) of the body tissue (°C).

10

The inclusion of the heat required to warm the tissue to the peak temperature (T) in the control strategy is graphically represented at 68 in FIG. 4. With respect to the control strategy, the effects of the heat required to warm the tissue to the peak temperature (T) 68 should be taken into account before flow rate Q adjustment being undertaken to detect the location of the line of onset of boiling 76. In other words, the flow rate Q should not be decreased in response to a lack of boiling before at least a quasi-steady state has been achieved as the location of the line of onset of boiling 76 will continue to move during the transitory period. Otherwise, if the flow rate Q is decreased during the transitory period, it may be possible to decrease the flow Q to a point past the line of onset of boiling 76 and continue past the 100% boiling line 80 which is undesirable. In other words, as temperature (T) is approached the heat 68 diminishes towards zero such that the lines of constant boiling shift to the left towards the Y-axis.

20 FIG. 5 is an exemplary graph of flow rate Q versus % boiling for a situation where the RF power P is 75 watts. The percent boiling % is represented on the X-axis, and the saline flow rate Q (cc/min) is represented on the Y-axis. According to this example, at 100 % boiling the most desirable predetermined saline flow rate Q is 2 cc/min. Also according to this example, flow rate Q versus % boiling at the remaining points of the graft illustrates a non-linear relationship as follows:

30

Table 1 – % Boiling and Flow Rate Q (cc/min) at RF Power P of 75 watts

	0%	17.4
	10%	9.8
	20%	6.8
	30%	5.2
	40%	4.3
	50%	3.6
	60%	3.1
	70%	2.7
	80%	2.4
	90%	2.2
	100%	2.0

Typical RF generators used in the field have a monopolar power selector switch to 300 watts of power, and on occasion some have been found to be selectable up to 400 watts of power. In conformance with the above methodology, at 0% boiling with a corresponding power of 300 watts, the calculated flow rate Q is 5 69.7 cc/min and with a corresponding power of 400 watts the calculated flow rate Q is 92.9 cc/min. Thus, when used with typical RF generators in the field, a fluid flow rate Q of about 100 cc/min or less with the present invention is expected to suffice for the vast majority of applications.

As discussed herein, RF power delivery to tissue can be unpredictable and 10 vary with time, even though the generator has been "set" to a fixed wattage. The schematic graph of FIG. 6 shows the general trends of the output curve of a typical general-purpose generator, with the output power changing as load impedance Z changes. Load impedance Z (in ohms) is represented on the X-axis, and generator 15 output power P (in watts) is represented on the Y-axis. In the illustrated embodiment, the electrosurgical power (RF) is set to 75 watts in a bipolar mode. As shown in the figure, the power will remain constant as it was set as long as the impedance Z stays between two cut-offs, low and high, of impedance, that is, for example, between 50 ohms and 300 ohms in the illustrated embodiment. Below 20 load impedance Z of 50 ohms, the power P will decrease, as shown by the low impedance ramp 28a. Above load impedance Z of 300 ohms, the power P will decrease, as shown by the high impedance ramp 28b. This change in output is 25 invisible to the user of the generator and not evident when the generator is in use, such as in an operating room.

FIG. 7 shows the general trend of how tissue impedance generally changes 30 with time for saline-enhanced electrosurgery. As tissue heats up, the temperature coefficient of the tissue and saline in the cells is such that the tissue impedance decreases until a steady-state temperature is reached upon which time the impedance remains constant. Thus, as tissue heats up, the load impedance Z decreases, potentially approaching the impedance Z cut-off of 50 ohms. If tissue is sufficiently heated, such that the low impedance cut-off is passed, the power P decreases along 35 the lines of the low impedance ramp 28a of FIG. 6.

Combining the effects shown in FIG. 6 and FIG. 7, it becomes clear that when using a general-purpose generator set to a "fixed" power, the actual power delivered can change dramatically over time as tissue heats up and impedance drops. Looking at FIG. 6, if the impedance Z drops from 100 to 75 ohms over time, the power output would not change because the curve is "flat" in that region of impedances. If, however, the impedance Z drops from 75 to 30 ohms one would

transgress the low impedance cut-off and "turn the corner" onto the low impedance ramp 28a portion of the curve and the power output would decrease dramatically.

According to one exemplary embodiment of the invention, the control device, such as flow rate controller 11, receives a signal indicating the drop in actual power delivered to the tissue and adjusts the flow rate Q of saline to maintain the tissue/electrode interface at a desired temperature. In a preferred embodiment, the drop in actual power P delivered is sensed by the power measurement device 8 (shown in FIG. 1), and the flow rate Q of saline is decreased by flow rate controller 11 (also shown in FIG. 1). Preferably, this reduction in saline flow rate Q allows the tissue temperature to stay as hot as possible without desiccation. If the control device was not in operation and the flow rate Q allowed to remain higher, the tissue would be over-cooled at the lower power input. This would result in decreasing the temperature of the tissue at the treatment site and lead to longer treatment time.

Flow rate controller 11 of FIG. 1 can include a delay mechanism, such as a timer, to automatically keep the saline flow on for several seconds after the RF is turned off to provide a post-coagulation cooling of the tissue or "quench," which can increase the strength of the tissue seal. Flow rate controller 11 can also include a delay mechanism, such as a timer, to automatically turn on the saline flow several seconds before the RF is turned on to inhibit the possibility of undesirable effects as tissue desiccation, electrode sticking, char formation and smoke production.

Optionally, flow rate controller 11 can include a low level flow standby mechanism, such as a valve, which continues the saline flow at a standby flow level (which prevents the flow rate from going to zero when the RF power is turned off) below the surgical flow level ordinarily encountered during use of the electrosurgical device 5.

An exemplary electrosurgical device of the present invention which may be used in conjunction with the system of the present invention is shown at reference character 5a in FIG. 9, and more particularly in FIGS. 9-13. While various electrosurgical devices of the present invention are described with reference to use with the remainder of the system of the invention, it should be understood that the description of the combination is for purposes of illustrating the remainder of the system of the invention only. Consequently, it should be understood that the electrosurgical devices of the present invention can be used alone, or in conjunction with the remainder of the system of the invention, or that a wide variety of electrosurgical devices can be used in connection with the remainder of the system of the invention. The electrosurgical devices disclosed herein are preferably further configured for both open and minimally invasive surgery, such as laparoscopic

surgery. For laparoscopic surgery, the devices are preferably configured to fit through either a 5 mm or 12 mm trocar cannula.

As shown in FIG. 8, electrosurgical device 5a may be used in conjunction with a cannula as illustrated at reference character 19, during laparoscopic surgery such as, for example, a laparoscopic cholecystectomy. Cannula 19 comprises a proximal portion 19a separated from a distal portion 19b by an elongated rigid shaft portion 19c. Proximal portion 19a of cannula 19 preferably comprises a head portion 19d connected to rigid shaft portion 19c, preferably by threaded engagement. Most importantly, cannula 19 has a working channel 19e which extends through head portion 19d and shaft portion 19c from proximal portion 19a to distal portion 19b of cannula 19. In one particular embodiment, during insertion into cannula 19, electrosurgical device 5a is configured to enter the proximal end of working channel 19e, move along the channel 19e distally, and then be extended from the distal end of the working channel 19e. In the same embodiment, during retraction from cannula 19, electrosurgical device 5a is configured to enter the distal end of working channel 19e, move along the channel 19e proximally, and then be removed from the proximal end of working channel 19e.

Referring back to FIG. 9, as shown electrosurgical device 5a is a monopolar electrosurgical device. Electrosurgical device 5a preferably includes a rigid, self-supporting, hollow shaft 17, a proximal handle comprising mating handle portions 20a, 20b and a tip portion as shown by circle 45. Handle 20a, 20b is preferably made of a sterilizable, rigid, non-conductive material, such as a polymer (e.g., polycarbonate). As shown in FIGS. 10 and 11, tip portion 45 includes a contact element preferably comprising an electrode 25 which, as shown, comprises a solid ball having a smooth, uninterrupted surface. Tip portion 45 also comprises a sleeve 82 having a uniform diameter along its longitudinal length, a spring 88 and a distal portion of shaft 17. As shown in FIG. 10, the longitudinal axis 31 of the tip portion 45 may be configured at an angle A relative to the longitudinal axis 29 of the proximal remainder of shaft 17. Preferably, angle A is about 5 degrees to 90 degrees, and more preferably, angle A is about 8 degrees to 45 degrees.

As shown in FIGS. 10 and 11, for electrosurgical device 5a, electrode 25 generally has a spherical shape with a corresponding spherical surface, a portion 42 of which is exposed to tissue 32 at the distal end of device 5a. When electrode 25 is in the form of a sphere, the sphere may have any suitable diameter. Typically, the sphere has a diameter in the range between and including about 1 mm to about 7 mm, although it has been found that when a sphere is larger than about 4 mm or less than about 2 mm tissue treatment can be adversely effected (particularly tissue treatment time) due to an electrode surface that is respectively either too large or to

small. Thus, preferably the sphere has a diameter in the range between and including about 2.5 mm to about 3.5 mm, more preferably, about 3 mm.

It is understood that shapes other than a sphere can be used for the contact element. Examples of such shapes include oblong or elongated shapes. However, 5 as shown in FIGS. 10 and 11, preferably a distal end surface of electrosurgical device 5a provides a blunt, rounded surface which is non-pointed and non-sharp as shown by electrode 25.

As shown in FIGS. 10 and 11, electrode 25, is preferably located in a cavity 81 of a cylindrical sleeve 82 providing a receptacle for electrode 25. Among other 10 things, sleeve 82 guides movement of electrode 25. Among other things, sleeve 82 also functions as a housing for retaining electrode 25.

Also as shown in FIG. 11, a portion 44 of electrode 25, is retained within cavity 81 while another portion 43 extends distally through the fluid outlet opening provided by circular fluid exit hole 26. Also as shown, sleeve 82 is connected, 15 preferably via welding with silver solder, to the distal end 53 of shaft 17. For device 5a, electrode 25, sleeve 82 and shaft 17 preferably include, and more preferably are made at least almost essentially of, an electrically conductive metal, which is also preferably non-corrosive. A preferred material is stainless steel. Other suitable metals include titanium, gold, silver and platinum. Shaft 17 preferably is stainless 20 steel hypo-tubing.

As for cavity 81, the internal diameter of cavity 81 surrounding electrode 25 is preferably slightly larger than the diameter of the sphere, typically by about 0.25 mm. This permits the sphere to freely rotate within cavity 81. Consequently, cavity 81 of sleeve 82 also preferably has a diameter in the range of about 1 mm to about 7 25 mm.

As best shown in FIGS. 11 and 12, in order to retain electrode 25, within the cavity 81 of sleeve 82, preferably the fluid exit hole 26, which ultimately provides a fluid outlet opening, of cavity 81 at its distal end 83 comprises a distal pinched region 86 which is reduced to a size smaller than the diameter of electrode 25, to 30 inhibit escape of electrode 25 from sleeve 82. More preferably, the fluid exit hole 26 has a diameter smaller than the diameter of electrode 25.

As best shown in FIG. 12, fluid exit hole 26 preferably has a diameter smaller than the diameter of electrode 25, which can be accomplished by at least one crimp 84 located at the distal end 83 of sleeve 82 which is directed towards the 35 interior of sleeve 82 and distal to the portion 44 of electrode 25 confined in cavity 81. Where one crimp 84 is employed, crimp 84 may comprise a single continuous circular rim pattern. In this manner, the contact element portion extending distally through the fluid outlet opening (i.e., electrode portion 43) provided by fluid exit

hole 26 has a complementary shape to the fluid outlet opening provided by fluid exit hole 26, here both circular.

As shown in FIG. 12, crimp 84 may have a discontinuous circular rim pattern where crimp 84 is interrupted by at least one rectangular hole slot 85 formed at the distal end 83 of sleeve 82. Thus, the fluid outlet opening located at the distal end of the device 5a may comprise a first portion (e.g., the circular fluid exit hole portion 26) and a second portion (e.g., the slot fluid exit hole portion 85). As shown in FIG. 12, preferably, crimp 84 comprises at least four crimp sections forming a circular rim pattern separated by four discrete slots 85 radially located there between at 90 degrees relative to one another and equally positioned around the fluid outlet opening first portion. Slots 85 are preferably used to provide a fluid outlet opening or exit adjacent electrode 25, when electrode 25 is fully seated (as discussed below) and/or when electrode 25 is not in use (i.e., not electrically charged) to keep surface portion 42 of the electrode surface of electrode 25 wet. Preferably, slots 85 have a width in the range between and including about 0.1 mm to 1 mm, and more preferably about 0.2 mm to 0.3 mm. As for length, slots 85 preferably have a length in the range between and including about 0.1 mm to 1 mm, and more preferably about 0.4 mm to 0.6 mm.

As shown in FIG. 12, the contact element portion extending distally through the fluid outlet opening (i.e., electrode portion 43) extends distally through the fluid outlet opening first portion (e.g., the circular fluid exit hole portion 26) and does not extend distally through the fluid outlet opening second portion (e.g., the slot fluid exit hole portion 85). In this manner an edge 91 of slot 85 remains exposed to tissue 32 to provide a tissue separating edge as discussed below.

It should be understood that the particular geometry of fluid outlet opening provided by the fluid exit hole located at the distal end of device 5a to the electrode is not critical to the invention, and all that is required is the presence of a fluid exit hole which provides fluid 24 as required. For example, fluid exit hole 26 may have an oval shape while electrode 25 has a different shape, such as a round shape.

As shown in FIG. 12, in addition to slot 85 providing a fluid exit, at least one edge 91 of slot 85 may provide a tissue separating edge adjacent a blunt surface (e.g., surface portion 42 of electrode 25) which may be used for blunt dissection when the electrosurgical device 5a is manipulated, particularly by rotating (e.g., twirling), abrading or impacting. When edge 91 is used in such regard, it is preferred that the edge comprise a sharp edge with a sharp angle which has not been rounded by, for example, a fillet.

Turning to the proximal end of the tip (comprising electrode 25, spring 88 and sleeve 82) of the device 5a, as shown in FIG. 11, preferably the portion of

sleeve 82 proximal to electrode 25, also has a proximal pinched region 87 which retains electrode 25 in the cavity 81 of sleeve 82 and inhibits escape of electrode 25 from the cavity 81 of sleeve 82, such as a diameter smaller than the diameter of electrode 25.

5 While distal pinched region 86 and proximal pinched region 87 may be used solely to support electrode 25, in its position of use, the electrode may be further supported by a compression spring 88 as shown in FIG. 11. The use of spring 88 is preferred to provide a variable length support within the working length of the 10 spring 88 for overcoming manufacturing tolerances (e.g., length) between the fixed supports (i.e., pinched regions 86 and 87) of sleeve 82. As for maintaining proper location of the spring 88, sleeve 82 also comprises a lumen 89 as shown in FIG. 11, which, in addition to providing a direct passage for fluid, provides a guide tube for 15 spring 88. Furthermore, the surface portion 60 of electrode 25, which contacts spring 88 may have a flat surface rather than a curvilinear surface to better seat the spring against electrode 25.

In addition to the above, spring 88 provides a multitude of functions and advantages. For example, the configuration of the distal pinched region 86, proximal pinched region 87 and spring 88 offers the ability to move electrode 25 distally and proximally within sleeve 82. As shown in FIG. 11, spring 88 is located 20 proximal to electrode 25 between a first load bearing surface comprising the electrode surface 60 and a second load bearing surface comprising the distal end 53 of shaft 17. In this manner, spring 88 can be configured to provide a decompression force to seat electrode 25 against the distal pinched region 86, in this case the perimeter edge 92 of crimp 84, prior to use of electrosurgical device 5a.

25 Conversely, upon application of electrode 25 against surface 22 of tissue 32 with sufficient force to overcome the compression force of the spring 88, spring 88 compresses and electrode 25 retracts proximally away from distal pinched region 86, in this case perimeter edge 92 of crimp 84, changing the position thereof. In the above manner, the contact element comprising electrode 25 is retractable into the 30 cavity 81 of the housing provided by sleeve 82 upon the application of a proximally directed force against surface 42 of the portion 43 of electrode 25 extending distally beyond the distal opening 26 located at the distal end 83 of the housing and spring 88 functions as a retraction biasing member.

By making electrode 25 positionable in the above manner via spring 88, 35 electrosurgical device 5a can be provided with a damper mechanism which dampens the force of electrode 25 on tissue 32 being treated.

Furthermore, electrode 25 which can be positioned as outlined above can comprise a fluid flow rate adjustment mechanism which incrementally increases the

area of fluid exit hole 26 and the corresponding fluid flow rate in response to the incremental proximal retraction of electrode 25. In such an instance, electrode 25 functions as a valve by regulating flow of fluid 24 through fluid exit hole 26.

In various embodiments, spring 88 may be used in conjunction with the distal pinched region 86 (e.g., crimp 84 comprising a single continuous circular pattern) to provide a fluid seal between electrode 25 and the distal pinched region 86 which stops fluid flow from the electrosurgical device 5a. In this manner, the electrosurgical device 5a may be used to provide both a wet electrode and dry electrode (i.e., when the fluid flow is on and off, respectively) with the energy and fluid provided sequentially as opposed to simultaneously.

Furthermore, in various embodiments of electrosurgical device 5a, an electrode 25 which can be positioned as outlined above can include a declogging mechanism. Such a mechanism can retract to provide access for unclogging fluid exit holes (e.g., 26 and 85), which may become flow restricted as a result of loose debris (e.g., tissue, blood, coagula) becoming lodged therein. For example, when a biasing force, such as from a handheld cleaning device (e.g., brush) or from pushing the distal tip against a hard surface such as a retractor, is applied to surface 42 of electrode 25 which overcomes the compression force of the spring 88 causing the spring 88 to compress and electrode 25 to retract, the tip of the handheld cleaning device may be extended into the fluid exit hole 26 for cleaning the fluid exit hole 26, perimeter edge 92, slot 85 and edge 91. Stated another way, electrode 25, which can be positioned as outlined, provides a methodology for declogging a fluid exit hole by increasing the cross-sectional area of the fluid exit hole to provide access thereto.

Additionally, in various embodiments of device 5a, spring 88 comprises an electrical conductor, particularly when electrode 25, is retracted to a non-contact position (i.e., not in contact) with sleeve 82.

In other embodiments, proximal pinched region 87 may comprise one or more crimps similar to distal pinched region 86, such that electrode 25 is retained in sleeve 82 both distally and proximally by the crimps. Also, in other embodiments, sleeve 82 may be disposed within shaft 17 rather than being connected to the distal end 53 of shaft 17. Also, in still other embodiments, sleeve 82 may be formed unitarily (i.e., as a single piece or unit) with shaft 17 as a unitary piece.

As best shown in FIGS. 10 and 11, electrode 25 is retained in sleeve 82 with a portion 43 of electrode 25 extending distally beyond distal end 83 of sleeve 82. As shown, preferably the surface 42 of this exposed portion 43 of electrode 25 is blunt and does not have any sharp corners. Also, the portion 43 of electrode 25 which extends distally beyond the distal end 83 of sleeve 82 is controlled by the shape of the fluid exit hole 26 in sleeve 82 in relation to the shape of electrode 25. In other

words, the portion 43 of electrode 25 that extends distally beyond distal end 83 of sleeve 82 is controlled by the contact of the electrode surface with the edge 92.

In locations where shaft 17 and sleeve 82 are electrically conductive (for device 5a, preferably shaft 17 and sleeve 82 are completely electrically conductive and do not comprise non-conductive portions) an electrical insulator 90 (i.e., comprising non-conductive or insulating material) preferably surrounds shaft 17 and sleeve 82 along substantially its entire exposed length (e.g., the portion outside the confines of the handle 20), terminating a short distance (e.g., at the proximal onset of crimp 84 or less than about 3 mm) from distal end 83 of sleeve 82. Insulator 90 preferably comprises a shrink wrap polymer tubing.

As with the other electrosurgical devices described within, a input fluid line 4b and a power source, preferably comprising generator 6 preferably providing RF power via cable 9, are preferably fluidly and electrically coupled, respectively, to the tip portion 45 of the electrosurgical device 5a.

As indicated above, device 5a comprises a monopolar device. For electrosurgical device 5a, electrode 25 provides an active electrode, while a ground pad dispersive electrode 125 (shown in FIG. 45) located on the patient, typically on the back or other suitable anatomical location, provides a return electrode. Preferably, both electrodes are electrically coupled to generator 6 to form an isolated electrical circuit. Preferably the active electrode is coupled to generator 6 via a wire conductor from insulated wire cable 9 to the outer surface 18 of shaft 17 within the confines of handle 20a, 20b, typically through a switch such as 15a.

Switch 15a preferably comprises a dome switch having two electrical contacts. The contacts preferably comprise upper and lower contacts disposed on a platform in overlying relationship. Preferably the upper contact comprises a dome shaped configuration overlying and spaced from the lower contact which is flat. Preferably the contacts are spaced from one another by virtue of the domed configuration of the upper contact when the switch 15a is in an undepressed position, thus creating an open control circuit relative to switch 15a. However, when the upper contact is pressed into a depressed position, the upper contact comes into contact with the lower contact thus closing the hand switch control circuit. The presence of the closed control circuit is then sensed by generator 6 which then provides power to the electrode 25.

When a depression force is removed from the upper contact, the contact returns to its undepressed domed position as a result of its resiliency or elastic memory, thus returning switch 15a to its undepressed position and reopening the hand control circuit. The presence of the open control circuit is then sensed by the generator which then stops providing power to electrode 25.

In some embodiments, shaft 17 may be made of an electrical non-conducting material except for a portion at its distal end 53 that comes in contact with sleeve 82. This portion of shaft 17 that contacts sleeve 82 should be electrically conducting. In this embodiment, the wire conductor from insulated wire cable 9 extends to this 5 electrically conducting portion of shaft 17. In still other embodiments, shaft 17 may completely comprise a non-conducting material as where the wire conductor from insulated wire cable 9 extends directly to sleeve 82.

With respect to the fluid coupling, fluid 24 from the fluid source 1 preferably is communicated from fluid source 1 through a flexible, polyvinylchloride (PVC) 10 outlet fluid line 4a to a flexible, polyvinylchloride (PVC) inlet fluid line 4b connected to electrosurgical device 5a. Outlet fluid line 4a and inlet fluid line 4b are preferably connected via a male and female mechanical fastener configuration; a preferred such connection is a Luer-Lok® connection from Becton, Dickinson and Company. The lumen of the inlet line is then preferably interference fit over the 15 outside diameter of shaft 17 to provide a press fit seal there between. An adhesive may be used there between to strengthen the seal. Fluid 24 is then communicated down lumen 23 of shaft 17 through lumen 89 and cavity 81 of sleeve 82 where it is expelled from around and on the exposed surface 42 of electrode 25. This provides a wet electrode for performing electrosurgery.

As shown in FIG. 13, during use of electrosurgical device 5a, typically a 20 fluid coupling 30 preferably comprising a discrete, localized web and more preferably comprising a triangular shaped web or bead portion providing a film of fluid 24 is provided between surface 22 of tissue 32 and electrode 25. When the user of electrosurgical device 5a places electrode 25 at a tissue treatment site and 25 moves electrode 25 across the surface 22 of the tissue 32, fluid 24 is expelled around and on surface 42 of electrode 25 at the distal end 83 of sleeve 82 and onto the surface 22 of the tissue 32 via coupling 30. The fluid 24, in addition to providing an electrical coupling between electrosurgical device 5a and tissue 32, lubricates surface 22 of tissue 32 and facilitates the movement of electrode 25 across surface 30 22 of tissue 32. During movement of electrode 25, electrode 25 typically slides across surface 22 of tissue 32, but also may rotate as electrode 25 moves across surface 22 of tissue 32. Typically the user of the electrosurgical device 5a slides the electrode across surface 22 of tissue 32 back and forth with a painting motion while using fluid 24 as, among other things, a lubricating coating. Preferably the thickness 35 of the fluid 24 between the distal end surface of electrode 25 and surface 22 of tissue 32 at the outer edge of the coupling 30 is in the range between and including about 0.05 mm to 1.5 mm, more preferably in the range between and including about 0.1

mm to 0.3 mm. Also preferably, in certain embodiments, the distal end tip of electrode 25 contacts surface 22 of tissue 32 without any fluid 24 in between.

Another exemplary electrosurgical device is shown at reference character 5b in FIGS 14-16. In this embodiment, electrical insulator 90 preferably terminates proximally to sleeve 82 where sleeve 82 is connected to the distal end 53 of shaft 17. In certain embodiments where sleeve 82 is formed unitary shaft 17, electrical insulator 90 preferably terminates proximally to proximal pinched region 87. In this manner, in addition to the spherical surface portion 42 of electrode 25 and the narrowing surface portion 41, here conical, of sleeve 82 being used for treating tissue 32 when exposed thereto, a cylindrical surface 40 of a cylindrical portion 39 of sleeve 82 and a broadening surface portion 47 of broadening portion 54, here both conical, of sleeve 82 also function as electrode surfaces for treating tissue. Thus, the electrode exposed to tissue 32 now comprises a cylindrical surface portion 40 and a broadening surface portion 47 in addition to the spherical surface portion 42 and the narrowing surface portion 41, with the cylindrical surface portion 40 substantially increasing the surface area of the electrode. As a result, electrode 25 has surfaces which are parallel and perpendicular to the longitudinal axis 31 of tip portion 45, and more particularly, sleeve 82 of electrosurgical device 5b. In the above manner, front end use (e.g., surfaces 41 and 42), sideways use (e.g., surface 40 and 47), or oblique use (e.g., surfaces 40, 41 and 42) of electrosurgical device 5b is facilitated.

In the above manner, tip portion 45 now includes a first tissue treating surface (e.g., distal end spherical surface 42) and a second tissue treating surface (e.g., side surface 40). As discussed above, preferably the first tissue treating surface is configured for blunt dissection while the second tissue treating surface is configured for coagulation. Additionally, tip portion 45 also has a third tissue treating surface (e.g., surface 41) located between the first tissue treating surface (e.g., surface 42) and a second tissue treating surface (e.g., surface 40). Furthermore, tip portion 45 also has a fourth tissue treating surface (e.g., surface 47) located proximal and adjacent to surface 40.

With device 5a, when electrode 25 is placed directly in contact with surface 22 of tissue 32, tissue 32 may occlude fluid flow from fluid exit holes 26, 85 located at the distal end of device 5a. Consequently, for device 5b fluid exit holes 93, 94 may be located in the cylindrical side portion 39 of sleeve 82, either proximal or adjacent to electrode 25, and either in addition to or as an alternative to fluid exit holes 26, 85.

As shown in FIGS. 14 and 15, at least one fluid exit hole 93 is preferably formed in the cylindrical longitudinal side surface 40 and through the wall of side portion 39 of sleeve 82 adjacent to electrode 25 when electrode 25 is fully seated.

Furthermore, preferably at least one fluid exit hole 94 is formed in the cylindrical side portion 39 of sleeve 82 proximal to electrode 25 when electrode 25 is fully seated.

Preferably, holes 93, 94 each comprise more than one hole which are equally spaced radially in a circular pattern around the longitudinal axis 31 of tip portion 45, and more particularly sleeve 82. More preferably, holes 93, 94 each comprise four discrete holes equally spaced 90 degrees around the cylindrical side portion 39 of sleeve 82. Preferably holes 93, 94 have a diameter in the range between and including about 0.1 mm to 1.0 mm, and more preferably have a length in the range between and including about 0.2 mm to 0.6 mm.

Electrode 25, which can be positioned as outlined above, can comprise not only a valve for regulating fluid flow from the fluid exit holes, such as fluid exit hole 26, but also comprise a valve which, while opening one fluid flow exit, simultaneously closes another fluid flow exit. For example, as electrode 25 retracts proximally, fluid exit hole 26 is opened while fluid exit hole 93 is closed. Stated another way, an electrode 25 which can be positioned as outlined above can provide a mechanism for altering the size and/or location of the fluid exit holes during use of electrosurgical device 5b which may be necessary, for example, to direct fluid to a particular tissue location or balance fluid flow among the fluid exit outlets.

Thus, as shown in FIGS. 14 and 15, surfaces 40, 41 and 47 of sleeve 82, and surface 42 of electrode 25 are all active electrode surfaces and can provide electrical energy to tissue 32. Portions of this combined electrode surface can be wet by fluid flow from holes 26, 94 or 93, as well as from the hole slots 85 in crimp 84 adjacent electrode 25.

The holes 94, 93 in the cylindrical sleeve 82 of the overall electrode surface are intended to assure that fluid 24 is provided to the smooth, less rough, atraumatic sides of the electrode that may be predominately used for tissue coagulation and hemostasis (e.g., surfaces 40 and 47) rather than blunt dissection (e.g., surfaces 41 and 42). The most distal portion of the device may have a more rough, but also wetted, electrode surface that can blunt dissect as well as coagulate tissue.

The electrode configuration shown in FIGS. 14 and 15 is particularly useful to a surgeon performing a liver resection. Once the outer capsule of the liver is scored with a dry bovie blade along the planned line of resection the distal tip of tip portion 45 is painted back and forth along the line, resulting in coagulation of the liver parenchyma beneath the scored capsule. As the tissue is coagulated under and around the electrode surfaces 40, 41 and 42, the electrode is used to blunt dissect into the coagulated parenchyma, with edge 91 of slots 85 around crimp 84 providing

roughness elements that aid in disrupting the tissue 32 and enabling the parting of tissue 32.

As shown in FIG. 16, the device 5b can be used in a crevice 97 of tissue 32 to blunt dissect tissue 32 and coagulate it at the same time. Blunt dissection is preferred over sharp dissection, such as with a blade or scissors, since blunt dissection is less likely to tear or damage the larger blood vessels or other vessels. Once identified by blunt dissection, very large vessels can be safely clipped, tied with suture or sealed with some other device. If the larger vessels are not thus first "skeletonized" without being damaged by blunt dissection, they may bleed profusely and require much more time to stop the bleeding. The device can also be used to coagulate first without simultaneous blunt dissection, and then blunt dissect in a separate step.

This technique can also be used on other parenchymal organs such as the pancreas, the kidney, and the lung. In addition, it may also be useful on muscle tissue and subcutaneous fat. Its use can also extend to benign tumors, cysts or other tissue masses found in the urological or gynecological areas. It would also enable the removal of highly vascularized tumors such as hemangiomas.

In FIG. 16 the zone 99 identifies the part of the electrode that has the ability to blunt dissect and coagulate, and the zone 98 identifies the part that is intended primarily for coagulation and hemostasis. The line 100 indicates the depth of the zone of tissue that is coagulated, typically from 3 mm to 5 mm deep.

For the devices disclosed herein, the presence of various fractions of boiling can be visually estimated by the naked eye, or by detecting changes in electrical impedance. FIG. 17 shows a graph of electrical impedance Z versus time t. The impedance spikes 101 shown in FIG. 17 occur at a frequency of about 1 cycle per second and with an amplitude that is on the same order as the baseline impedance. This frequency is shown in FIG. 17 as the interval 102 between successive impedance spikes. Impedance is directly measurable by dividing the voltage by the current as previously described. The use of electrical impedance to detect the onset of tissue dessication when impedance rises dramatically as a result of being heated to the point of smoking and charring, but not to detect the presence of boiling, is described above.

Shown in FIG. 18 is the qualitative nature of the boiling as the % boiling increases, indicated by the small figures for each of five exemplary "regimes" of boiling. In each small figure a portion of the tip of the tip portion 45 of device 5a is shown in close proximity to tissue 32. As boiling begins in regime 104, there are few small bubbles 37 of vapor in the conductive fluid 24, here saline, of coupling 30. As the percentage of boiling increases at regime 106 there are a larger number

of small bubbles 37. As the percentage boiling increases further at regime 107, the bubbles 37 become much larger. At even higher percentage boiling at regime 108 intermittent threads of saline form and are quickly boiled off. Finally, at the highest level of regime 109, drops 36 of saline are instantly boiled upon contacting the hot surface 22 of tissue 32 and arcing occurs from the metal to tissue 32.

5 Returning to FIGS. 14 and 15, fluid outlet openings are provided by substantially linear through holes 93, 94 which provide conductive fluid 24 to the treatment site. However, in an alternative embodiment, as shown in FIG. 19, fluid outlet openings in sleeve 82 may be provided by holes in the form of tortuous and
10 interconnected pathways 59, which are formed in a material pervious to the passage of fluid 24, therethrough, such as a porous material. The discrete, linear through holes 93, 94 may be either supplemented with or replaced by a plurality of tortuous, interconnected pathways 59 formed in the porous material which, among other things, provides porous surfaces 40, 41 and 47 to more evenly distribute fluid flow
15 and provide the conductive fluid 24 to tissue 32 at the treatment site. According to the invention, all or a portion of sleeve 82 may comprise a material pervious to the passage of fluid 24 therethrough as disclosed herein.

In certain embodiments, the contact element, here electrode 25 may also
20 comprise a material pervious to the passage of fluid 24, therethrough, such as a porous material (e.g., metal, polymer or ceramic) to provide the tortuous pathways 59. In these embodiments, the porous structure of electrode 25 allows fluid 24 to not only pass around electrode 25 on the outer porous surface 42 to be expelled, but also allows fluid 24 to pass through electrode 25, to be expelled. According to the invention, all or a portion of the electrodes or any particular electrodes for treating
25 tissue 32 may comprise a material pervious to the passage of fluid 24 therethrough as disclosed herein.

Where the contact element and sleeve provide electrodes for treating tissue and comprise a porous material, preferably the porous material further comprises porous metal. Porous sintered metal is available in many materials (such as, for
30 example, 316L stainless steel, titanium, Ni-Chrome) and shapes (such as cylinders, discs, plugs) from companies such as Porvair, located in Henderson, NC.

While the electrode provided by contact element and/or sleeve preferably comprises an electrically conductive material such as metal, a non-electrically conductive porous contact element and/or sleeve, such as porous polymers and
35 ceramics, can be used to replace an electrically conductive contact element and/or sleeve. While the porous polymers and ceramics are generally non-conductive, they may also be used to conduct the RF energy through the porous polymer and ceramic

thickness and porous surface to the tissue to be treated by virtue of conductive fluid 24 contained within the plurality of interconnected tortuous pathways 59.

Preferably the porous material provides for the wicking (i.e., drawing in of fluid by capillary action or capillarity) of the fluid 24 into the pores of the porous material. In order to promote wicking of the fluid 24 into the pores of the porous material, preferably the porous material, and in particular the surface of the tortuous pathways, is hydrophilic. The porous material may be hydrophilic with or without post treating (e.g., plasma surface treatment such as hypercleaning, etching or micro-roughening, plasma surface modification of the molecular structure, surface chemical activation or crosslinking), or made hydrophilic by a coating provided thereto, such as a surfactant.

Though not preferable, it is not necessary that fluid coupling 30 of fluid 24 be present in between the metal electrode surfaces (e.g., 40, 41, 42) and tissue 32 at all locations of tissue treatment and there may be points of direct tissue contact by the electrode surfaces without any fluid coupling 30 therebetween. In such an instance, the convective cooling of the metal electrode by flowing saline is often sufficient to keep the metal electrode and tissue contacting the metal electrode at or below a temperature of 100 °C. In other words, heat may be also first dissipated from tissue 32 to the electrodes by conduction, then dissipated from the electrodes to the fluid 24 by convection.

Preferably the relationship between the material for electrodes particularly their surfaces (e.g., 40, 41, 42, 47), and fluid 24 throughout the various embodiments should be such that the fluid 24 wets the surface of the electrodes to form a continuous thin film coating thereon (for example, see FIG. 21) and does not form isolated rivulets or circular beads (e.g., with a contact angle, θ greater than 90 degrees) which freely run off the surface of the electrode. Contact angle, θ , is a quantitative measure of the wetting of a solid by a liquid. It is defined geometrically as the angle formed by a liquid at the three phase boundary where a liquid, gas and solid intersect. In terms of the thermodynamics of the materials involved, contact angle θ involves the interfacial free energies between the three phases given by the equation $\gamma_{LV} \cos \theta = \gamma_{SV} - \gamma_{SL}$ where γ_{LV} , γ_{SV} and γ_{SL} refer to the interfacial energies of the liquid/vapor, solid/vapor and solid/liquid interfaces, respectively. If the contact angle θ is less than 90 degrees the liquid is said to wet the solid. If the contact angle is greater than 90 degrees the liquid is non-wetting. A zero contact angle θ represents complete wetting. Thus, preferably the contact angle is less than 90 degrees.

For clarification, while it is known that the contact angle θ may be defined by the preceding equation, in reality contact angle θ is determined by a various

models to an approximation. According to publication entitled "Surface Energy Calculations" (dated September 13, 2001) from First Ten Angstroms (465 Dinwiddie Street, Portsmouth, Virginia 23704), there are five models which are widely used to approximate contact angle θ and a number of others which have small followings. The five predominate models and their synonyms are: (1) Zisman critical wetting tension; (2) Girifalco, Good, Fowkes, Young combining rule; (3) Owens, Wendt geometric mean; (4) Wu harmonic mean; and (5) Lewis acid/base theory. Also according to the First Ten Angstroms publication, for well-known, well characterized surfaces, there can be a 25% difference in the answers provided for the contact angle θ by the models. Also for clarification, any one of the five predominate models above which calculates a contact angle θ within a particular range of contact angles θ or the contact angle θ required of a particular embodiment of the invention should be considered as fulfilling the requirements of the embodiment, even if the remaining four models calculate a contact angle θ which does not fulfill the requirements of the embodiment.

The effects of gravity and surface tension tend to wick the fluid 24, here saline, around the circumference of the cylindrical sleeve 82 to preferably cover the entire active electrode surface. More specifically, the effects of gravity and surface tension on fluid 24 which is located on the electrode surfaces may be modeled by the Bond number N_{BO} . Bond number N_{BO} measures the relationship of gravitational forces to surface tension forces and may be expressed as:

$$N_{BO} = \rho L^2 g / \sigma \quad (7)$$

where:

- ρ = Density of the saline fluid (approximately 1.0 gm/cm³);
 L = Droplet diameter (cm);
 g = Gravitational acceleration (980 cm/s²); and
 σ = Surface tension (approximately 72.8 dynes/cm @ 20° C)

For a Bond number $N_{BO} = 1$, the droplet diameter is equal to about .273 cm or about 2.7 mm, which is in the same order of magnitude as the preferred size of the electrode. For the purposes of the present invention, preferably Bond number N_{BO} for a droplet of fluid 24 on a surface of electrode 25 is preferably less than 1.

Another tip portion of an exemplary electrosurgical device 5c of the present invention which may be used in conjunction with the system of the present invention is shown at reference character 45 in FIGS 20-24. As best shown in FIGS. 20 and 21, the separate sleeve 82 of embodiments 5a and 5b has been eliminated from tip portion 45 of device 5c. Consequently, the contact element, still preferably

comprising an electrode 25, is assembled directly with the shaft 17. Electrode 25 is preferably assembled (e.g., mechanically connected via press fit, mechanical connector, threaded, welded, adhesively bonded) adjacent the distal end 53 of shaft 17. In certain embodiments, electrode 25 preferably is detachably assembled to the shaft 17 such that it may be removed from the shaft 17, preferably manually by human hand, so that the shaft 17 may be used with multiple different contact elements/electrodes, or the shaft 17 may be reusable and used with disposable contact elements/electrodes.

As shown in FIGS. 20-24, electrode 25 preferably comprises an enlarged head portion comprising a spherical portion 43 and a corresponding spherical surface portion 42 located at the distal end of the device 5c which provide a smooth, blunt contour outer surface. More specifically, as shown, the spherical portion 43 and spherical surface portion 42 further provide a domed, hemisphere (i.e., less than a full sphere) and hemispherical surface portion comprising preferably about 180 degrees.

Also as shown in FIGS. 20-24, the enlarged head portion of electrode 25 preferably also comprises a cylindrical portion 39 and a corresponding cylindrical surface portion 40 located proximal and adjacent to the spherical portion 43 and spherical surface portion 42, respectively.

Further continuing with FIGS. 20-24, electrode 25 preferably comprises a connector portion, preferably comprising a shank 46, which connects the remainder of electrode 25 to the shaft 17. Among other things, the connector portion of electrode 25 is preferably configured to form a connection with a mating connector portion of the shaft 17. As shown, preferably the shank portion 46 is configured to extend into cavity 50 of shaft 17 which comprises a cylindrical receptacle and provides the mating connector portion for shank 46. More preferably, surface 48 of the shank portion 46 is configured to mate against and form an interference fit with surface 52 of cavity 50 to provide the connection.

Continuing with FIGS. 20-24, shank portion 46 is preferably cylindrical and located proximal and adjacent to a neck portion 56. As shown, neck portion 56 comprises a cylindrical portion 57 (having a corresponding cylindrical surface portion 58) and a broadening portion 54 (having a corresponding broadening surface portion 47). Here broadening portion 54 and corresponding broadening surface portion 47 are both spherical, and more specifically comprise a domed, hemisphere and hemispherical surface portion comprising preferably about 180 degrees, located proximal and adjacent to the cylindrical portion 39 and cylindrical surface portion 40.

Preferably, cylindrical portion 39 has a diameter in the range between and including about 1 mm to about 7 mm; although it has been found that when cylindrical portion 39 is larger than about 4 mm or less than about 2 mm, tissue treatment can be adversely effected (particularly tissue treatment time) due to an electrode surface that is respectively either to large or to small. Thus, preferably the cylindrical portion 39 has a diameter in the range between and including about 2.5 mm to about 3.5 mm, and more preferably, about 3 mm.

With respect to length, preferably cylindrical portion 39 has a length in the range between and including about 2 mm to about 8 mm, and more preferably has a length in the range between and including about 3 mm to about 5 mm. Even more preferably, cylindrical portion 39 has a length of about 4.5 mm.

As shown in FIGS. 20-24, the cylindrical portion 57 of neck portion 56 preferably has a cross-sectional dimension, here diameter, greater than the cross-sectional dimension, here also diameter, of the shank 46. In this manner, in certain embodiments, the proximal end of the neck portion 56 may be located adjacent and in contact with the distal end 53 of shaft 17. Preferably, cylindrical portion 57 has a diameter in the range between and including about 2 mm to about 2.5 mm and the shank 46 has a diameter in the range between and including about 1.4 mm to about 1.9 mm. More preferably, cylindrical portion 57 has a diameter of about 2.2 mm and the shank 46 has a diameter of about 1.6 mm.

With respect to length, preferably cylindrical portion 57 has a length in the range between and including about 1 mm to about 8 mm, and more preferably has a length in the range between and including about 3 mm to about 5 mm. Even more preferably, cylindrical portion 57 has a length of about 4 mm. Shank 46 preferably has a length in the range between and including about 2 mm to about 6 mm, and more preferably has a length in the range between and including about 2.5 mm to about 5 mm. Even more preferably, shank 46 has a length of about 3 mm.

Also as shown in FIGS. 20-24, electrode 25 comprises at least one recess 64 which provides an elongated fluid flow channel for the distribution of fluid 24. The use of device 5c, and in particular recesses 64, for the distribution of fluid 24 is generally preferred to the fluid exit holes 93, 94 of device 5b in particularly deep tissue crevices 97.

As shown, electrode 25 preferably comprises a plurality of longitudinally directed recesses 64 and, more specifically, four recesses 64 equally spaced 90 degrees around the shank 46 and/or neck portion 56, both proximal of cylindrical portion 39. As best shown in FIG. 24, in certain embodiments, the recess 64 may comprise a first side wall 64a, a second opposing side wall 64b, and a bottom wall

64c. Preferably, recess 64 has a width in the range between and including about 0.1 mm to about 0.6 mm, and more preferably has a width of about 0.4 mm.

In use, when tissue 32 overlies and occludes the fluid outlet opening 55 of recess 64 for a portion of its longitudinal length, thus inhibiting fluid 24 from exiting therefrom, fluid 24 from recess 64 may still be expelled from the electrosurgical device 5c after flowing longitudinally in the channel 64 to a remote location where the channel 64 is unoccluded and uninhibited to fluid flow exiting therefrom.

On very rare occasion, it may be possible that the recess 64 may be occluded by tissue 32 completely along its longitudinal length, thus completely inhibiting fluid flow from exiting through opening 55. In order to overcome this problem, at least a portion of electrode 25 may comprise a material pervious to the passage of fluid 24, therethrough, such as a porous material described above.

Of the monopolar devices disclosed herein, device 5c has been found to be particularly useful to a surgeon performing a liver resection. Once the outer capsule of the liver is scored with a dry bovie blade along the planned line of resection, the distal tip of tip portion 45 is painted back and forth along the line, with radio frequency power and the flow of fluid 24 on, resulting in coagulation of the liver parenchyma. Once the tissue is coagulated under and around the electrode surface 42 and, as the device 5c enters crevice 97 as shown in FIG. 22, surfaces 40 and 42 of electrode 25 are used to blunt dissect the coagulated parenchyma. Blunt dissection of the coagulated parenchyma is performed by continuous abrading or splitting apart of the parenchyma with the substantially the same back and forth motion as coagulation and with the device 5c being held substantially in the same orientation as for coagulation of the liver parenchyma. However, with blunt dissection, the surgeon typically applies more force to the tissue. In various embodiments, once the liver parenchyma is coagulated, blunt dissection may be performed with or without the radio frequency power (i.e., on or off) and/or with or without the presence of fluid 24.

As shown in FIG. 25, in another embodiment of the electrosurgical device of the present invention, as shown at reference character 5d in FIG. 25, the walls 64a, 64b of recess 64, surface 48 of the shank portion 46, and/or the surfaces of the neck portion 56 of electrode 25 may be porous and connected by a plurality of tortuous pathways 59 in the porous material. Consequently, rather than flowing out of recess 64 from a direct fluid outlet opening 55, which may be occluded by tissue 32, the fluid 24 may exit indirectly from recess 64 by first flowing through tortuous pathways 59 of electrode 25 from side walls 64a, 64b of the recess 64 and then exit electrode 25 from surface 58, which may be in unoccluded by tissue 32.

Alternatively, if adjacent surface 58 of electrode 25 is also occluded by tissue 32, the

fluid 24 may continue to flow through tortuous pathways 59 of electrode 25 and exit electrode 25 from a surface 64a, 64b of a recess 64 or surface such as 40, 42, 47 or 58 which may be in unoccluded by tissue 32.

Where electrode 25 comprises a porous material, recess 64 may be either 5 supplemented with or replaced by the plurality of tortuous, interconnected passages 59 formed in the porous material as shown in FIG. 25. All or a portion of the electrodes can be porous according to the invention.

In other embodiments of the invention, recess 64 may comprise cross-sectional shapes other than rectangular shapes. For example, as shown in FIGS. 26-10 28 recess 64 comprises a semi-circular shape, a V-shape, or a U-shape respectively, or any combination thereof.

Returning to FIG. 21, in order to facilitate direct fluid communication of recess 64 with lumen 23 of shaft 17, preferably recesses 64 of device 5c are initiated within the confines of shaft 17. In other words, within the cavity 50 of shaft 17 15 proximal to distal end 53. As indicated above, the use of device 5c, and in particular recesses 64, for the distribution of fluid 24 is generally preferred to the fluid exit holes 93, 94 of device 5b in deep tissue crevices 97 where tissue 32 can occlude fluid flow from the fluid exit holes 93, 94 located in the cylindrical portion 39 of electrode 25. Also, since holes 93, 94 are not presented with a declogging 20 mechanism, such as provided for such as fluid exit holes 26 and 85, holes such as 93, 94 that can be simply occluded by ordinary tissue/electrode contact will sooner or later become irreversibly clogged.

As shown in FIG. 21, with device 5c fluid outlet openings 73 are provided by the structure of electrode 25 (i.e., recesses 64) at the distal end 53 of the shaft 17 25 which are protected and sheltered from contact and occlusion from surface 22 of tissue 32. Fluid outlet openings 73 of device 5c are protected from occlusion from surface 22 of tissue 32 as the structure of device 5c defining the openings 26 is at least partially configured for non-contact with surface 22 of tissue 32. More specifically, here the structure of the device defining the openings 73 is completely 30 configured for non-contact with surface 22 of tissue 32. Stated another way, the openings 73 are provided on the device 5c at a location removed from the tissue surface 22. Also, as shown, openings 26 are particularly sheltered from occlusion from surface 22 of tissue 32 by a portion of the shaft 17. Also as shown, openings 73 are formed substantially perpendicular to the surface 22 of tissue 32 and thus turned away from direct contact with surface 22 of tissue 32.

Another tip portion of an exemplary electrosurgical device 5e of the present invention which may be used in conjunction with the system of the present invention is shown at reference character 45 in FIGS. 29-30. As shown, the broadening

portion 54 has been eliminated and the cylindrical portion 39 has an equal cross-sectional dimension, here diameter, with the neck portion 56. Conversely, for device 5c, the cylindrical portion 39 has a cross-sectional dimension, there also diameter, greater than the cross-sectional dimension, there also diameter, of the neck portion 56.

Also as shown, the cylindrical portion 39 further comprises a rectilinear cylindrical portion 39a having a rectilinear cylindrical surface portion 40a and a curvilinear cylindrical portion 39b having a curvilinear cylindrical surface portion 40b. As shown, device 5e comprises the shape of a hockey stick. The cylindrical portion 39 for device 5c may be similarly arranged.

Another tip portion of an exemplary electrosurgical device 5f of the present invention which may be used in conjunction with the system of the present invention is shown at reference character 45 in FIGS 31-32. As shown, the cylindrical portion 39 has a cross-sectional dimension, here diameter, less than the cross-sectional dimension, here also diameter, of the neck portion 56. As shown the neck portion 56 includes a narrowing portion 49 with a corresponding narrowing surface portion 51, here both conical.

Also as shown, the cylindrical portion 39 further comprises a rectilinear cylindrical portion 39a having a rectilinear cylindrical surface portion 40a and a curvilinear cylindrical portion 39b having a curvilinear cylindrical surface portion 40b. Furthermore, as shown, the cylindrical portion 39, and more specifically at least one of the rectilinear cylindrical portion 39a and the curvilinear cylindrical portion 39b, comprises a portion of a hook. Preferably, as shown both the rectilinear cylindrical portion 39a and the curvilinear cylindrical portion 39b comprise portions of a hook. As shown, the hook further comprises an L-hook.

Another tip portion of an exemplary electrosurgical device 5g of the present invention which may be used in conjunction with the system of the present invention is shown at reference character 45 in FIGS 33-34. Similar to devices 5c-5f, the separate sleeve 82 of embodiments 5a and 5b has been eliminated from tip portion 45 of device 5g. Consequently, the contact element, still preferably comprising an electrode 25, is assembled directly with the shaft 17. Electrode 25 is preferably assembled (e.g., mechanically connected via a press fit, or interference fit, adjacent the distal end 53 of shaft 17).

As shown in FIGS. 33-34, electrode 25 preferably comprises a spherical portion 43 and a corresponding spherical surface portion 42 located at the distal end of the device 5g, which provided a smooth, blunt contour outer surface. More specifically, as shown, the spherical portion 43 and spherical surface portion 42

further provide a domed, hemisphere (i.e., less than a full sphere) and hemispherical surface portion comprising preferably about 180 degrees.

Also as shown in FIGS. 33-34, electrode 25 preferably also comprises a narrowing portion 49 and a corresponding narrowing surface portion 51, here both 5 conical, located proximal and adjacent to the spherical portion 43 and spherical surface portion 42, respectively. More preferably, as shown narrowing portion 49 and corresponding narrowing surface portion 51 comprise a conical portion in the form of a concentric cone shape, as opposed to device 5f where the conical portion provided by narrowing portion 49 and a corresponding narrowing surface portion 51 10 comprises an eccentric cone shape. Thus, in the above manner, spherical portion 43 and spherical surface portion 42 may provide a blunt apex to narrowing portion 49 and a corresponding narrowing surface portion 51, respectively.

Continuing with FIGS. 33-34, electrode 25 preferably also comprises a cylindrical portion 39 and a corresponding cylindrical surface portion 40 located 15 proximal and adjacent to the narrowing portion 49 and narrowing surface portion 51, respectively.

Similar to devices 5c-5f, electrode 25 preferably comprises a connector portion, preferably comprising a shank 46, which connects the remainder of electrode 25 to the shaft 17. Among other things, the connector portion of electrode 20 25 is preferably configured to form a connection with a mating connector portion of the shaft 17. As shown, preferably the shank portion 46 is configured to extend into cavity 50 of shaft 17 which comprises a cylindrical receptacle and provides the mating connector portion for shank 46. More preferably, surface 48 of the shank portion 46 is configured to mate against and form an interference fit with surface 52 25 of cavity 50 to provide the connection. Also similar to devices 5c-5f, shank portion 46 is preferably cylindrical and located proximal and adjacent to a neck portion 56.

As shown, similar to device 5c, neck portion 56 comprises a cylindrical portion 57 (having a corresponding cylindrical surface portion 58) and a broadening portion 54 (having a corresponding broadening surface portion 47). Here 30 broadening portion 54 and corresponding broadening surface portion 47 are both spherical, and more specifically comprise a domed, hemisphere and hemispherical surface portion comprising preferably about 180 degrees, located proximal and adjacent to the cylindrical portion 39 and cylindrical surface portion 40.

Similar to devices 5c-5f, the cylindrical portion 57 of neck portion 56 of 35 device 5g preferably has a cross-sectional dimension, here diameter, greater than the cross-sectional dimension, here also diameter, of the shank 46. In this manner, in certain embodiments, the proximal end of the neck portion 56 may be located adjacent and in contact with the distal end 53 of shaft 17.

Also similar to devices 5c-5f, preferably electrode 25 comprises at least one recess 64 which provides an elongated fluid flow channel for the distribution of fluid 24. As shown, electrode 25 preferably comprises a plurality of longitudinally directed recesses 64 and, more specifically, four recesses 64 equally spaced 90 degrees around the shank 46 and/or neck portion 56, both proximal of cylindrical portion 39.

Another tip portion of an exemplary electrosurgical device 5h of the present invention which may be used in conjunction with the system of the present invention is shown at reference character 45 in FIGS 35-36. Device 5h is similar to device 5g in all respects except that spherical portion 43 and spherical surface portion 42 have been eliminated and replaced with a distal end sharp point 71.

As shown in FIG. 36, the electrode 25 of device 5h comprises a simple cone. In other embodiments, electrode 25 may comprise other cone shapes. For example, as shown in FIGS. 37-40, the cone shape may comprise an ogive cone shape, an elliptical (prolate hemispheroid) cone shape, a bi-conic cone shape and parabolic series cone shapes, respectively, which all may be defined by mathematical equations as known in the art. Still other cone shapes may include power series cone shapes, Haake series cone shapes, Sears-Haake and Von Karman, which all may be defined by mathematical equations as known in the art.

Certain embodiments of the invention may be particularly configured for bipolar devices. For example, an exemplary bipolar electrosurgical device of the present invention which may be used in conjunction with the system of the present invention is shown at reference character 5i in FIGS. 41-43. With a bipolar device, the ground pad electrode located on the patient is eliminated and replaced with a second electrical pole as part of the device. An alternating current electrical circuit is then created between the first and second electrical poles of the device. Consequently, alternating current no longer flows through the patient's body to the ground pad electrode, but rather through a localized portion of tissue preferably between the poles of the bipolar device.

In certain embodiments, an exemplary bipolar surgical device of the present invention may comprise, among other things, multiple, substantially parallel, arms. As shown in FIG. 41, electrosurgical device 5i preferably includes two arms comprising rigid, self-supporting, hollow shafts 17a, 17b, a proximal handle comprising mating handle portions 20a, 20b and arm tip portions as shown by circles 45a, 45b. In this embodiment, shafts 17a, 17b preferably comprise thick walled hypo-tubing. In this manner, the shafts 17a, 17b have sufficient rigidity to maintain their form during use of the device without kinking or significant bending.

Preferably the arms of device 5i (comprising shafts 17a, 17b) are retained in position relative to each other by a mechanical coupling device comprising a collar 95 and inhibited from separating relative to each other. Collar 95 preferably comprises a polymer (e.g., acrylonitrile-butadiene-styrene or polycarbonate) and is 5 preferably located on the distal portion of the arms. More preferably, the collar 95 is located proximal the distal ends 53a, 53b of the shafts 17a, 17b. Preferably the collar 95 comprises two apertures 96a, 96b, preferably comprising opposing C-shapes, configured to receive a portion of the shafts 17a, 17b which are preferably snap-fit therein. Once the collar 95 is connected to the shafts 17a, 17b, preferably 10 by a snap-fit connection, the collar 95 may be configured to slide along the length of the shafts 17a, 17b as to adjust or vary the location of the collar 95 on the shafts 17a, 17b. Alternatively, the location of the collar 95 may be fixed relative to the shafts 17a, 17b by welding, for example.

Device 5i comprises a first arm tip portion 45a and a second arm tip portion 15 45b. As shown, preferably both first arm tip portion 45a and second arm tip portion 45b are each individually configured identical to tip portion 45 of device 5a. As a result, device 5i has two separate, spatially separated (by empty space) contact elements preferably comprising electrodes 25a, 25b.

As shown in FIG. 42, when device 5i is in use electrodes 25a, 25b are 20 laterally spaced adjacent tissue surface 22 of tissue 32. Electrodes 25a, 25b are connected to a source of alternating electrical current and alternating current electrical field is created between electrodes 25a and 25b. In the presence of alternating current, the electrodes alternate polarity between positive and negative charges with current flow from the positive to negative charge.

Similar to device 5a, for device 5i fluid 24 is communicated from a fluid 25 source 1 within the lumens 23a, 23b of the shafts 17a, 17b through the lumens 89a, 89b and cavities 81a, 81b of the sleeves 82a, 82b where it is expelled from around and on the surface 42a, 42b of the electrodes 25a, 25b.

As with use of device 5a, with use of device 5i fluid couplings 30a, 30b 30 preferably comprising discrete, localized webs and more preferably comprising a triangular shaped web or bead portion providing a film of fluid 24 between surface 22 of tissue 32 and electrodes 25a, 25b. When the user of electrosurgical device 5i places electrodes 25a, 25b at a tissue treatment site and moves electrodes 25a, 25b across surface 22 of tissue 32, fluid 24 is expelled around and on surfaces 42a, 42b 35 of electrodes 25a, 25b at the distal ends 83a, 83b of sleeves 82a, 82b and onto surface 22 of tissue 32 via couplings 30a, 30b. At the same time, RF electrical energy, shown by electrical field lines 130, is provided to tissue 32 at tissue surface 22 and below tissue surface 22 into tissue 32 through fluid couplings 25a, 25b.

As with device 5a, the fluid 24, in addition to providing an electrical coupling between the electrosurgical device 5i and tissue 32, lubricates surface 22 of tissue 32 and facilitates the movement of electrodes 25a, 25b across surface 22 of tissue 32. During movement of electrodes 25a, 25b, electrodes 25a, 25b typically slide across the surface 22 of tissue 32, but also may rotate as electrodes 25a, 25b move across surface 22 of the tissue 32. Typically the user of electrosurgical device 5i slides electrodes 25a, 25b across surface 22 of tissue 32 back and forth with a painting motion while using fluid 24 as, among other things, a lubricating coating. Preferably the thickness of the fluid 24 between the distal end surface of electrodes 25a, 25b and surface 22 of tissue 32 at the outer edge of couplings 30a, 30b is in the range between and including about 0.05 mm to 1.5 mm. More preferably, fluid 24 between the distal end surface of electrodes 25a, 25b and surface 22 of tissue 32 at the outer edge of coupling 30a, 30b is in the range between and including about 0.1 mm to 0.3 mm. Also preferably, in certain embodiments, the distal end tip of electrode 25 contacts surface 22 of tissue 32 without any fluid 24 in between.

As shown in FIG. 43, the fluid coupling for device 5i may comprise a conductive fluid bridge 27 between electrodes 25a, 25b which rests on surface 22 of tissue 32 and forms a shunt between electrodes 25a, 25b. Given this scenario, a certain amount of RF energy may be diverted from going into tissue 32 and actually pass between electrodes 25a, 25b via the conductive fluid bridge 27. This loss of RF energy may slow down the process of coagulating tissue and producing the desired hemostasis or aerostasis of the tissue.

In order to counteract the loss of energy through bridge 27, once enough energy has entered bridge 27 to boil fluid 24 of bridge 27, the loss of RF energy correspondingly decreases with the loss of bridge 27. Preferably energy is provided into fluid 24 of bridge 27 by means of heat dissipating from tissue 32.

Thus, where a high % boiling of conductive fluid 24 of bridge 24 is created, the loss of RF energy through bridge 27 may either be reduced or eliminated because all the fluid 24 of bridge 27 boils off or a large fraction of boiling creates enough disruption in the continuity of bridge 27 to disrupt the electrical circuit through bridge 27. Thus, one control strategy of the present invention is to reduce the presence of a conductive fluid shunt by increasing the % boiling of the conductive fluid.

Bipolar device 5i is particularly useful as non-coaptive tissue sealer and coagulator given it does not grasp tissue. Device 5i is particularly useful to surgeons to achieve hemostasis after dissecting through soft tissue as part of hip or knee arthroplasty. The tissue treating portions can be painted over the raw, oozing

surface 22 of tissue 32 to seal the tissue 32 against bleeding, or focused on individual larger bleeding vessels to stop vessel bleeding.

Bipolar device 5i is also useful to stop bleeding from the surface of cut bone tissue as part of any orthopaedic procedure that requires bone to be cut. Device 5i is particularly useful for these applications over monopolar device 5a as a much greater surface area 22 of tissue 32 may be treated in an equivalent period of time and with better controlled depth of the treatment.

As is well known, bone, or osseous tissue, is a particular form of dense connective tissue consisting of bone cells (osteocytes) embedded in a matrix of calcified intercellular substance. Bone matrix mainly contains collagen fibers and the minerals calcium carbonate, calcium phosphate and hydroxyapatite. Among the many types of bone within the human body are compact bone and cancellous bone. Compact bone is hard, dense bone that forms the surface layers of bones and also the shafts of long bones. It is primarily made of haversian systems which are covered by the periosteum. Compact bone contains discrete nutrient canals through which blood vessels gain access to the haversian systems and the marrow cavity of long bones. For example, Volkmann's canals which are small canals found in compact bone through which blood vessels pass from the periosteum and connect with the blood vessels of haversian canals or the marrow cavity. Bipolar device 5i disclosed herein may be particularly useful to treat compact bone and to provide hemostasis and seal bleeding vessels (e.g. by shrinking to complete close) and other structures associated with Volkmann's canals and Haversian systems.

In contrast to compact bone, cancellous bone is spongy bone and forms the bulk of the short, flat, and irregular bones and the ends of long bones. The network of osseous tissue that makes up the cancellous bone structure comprises many small trabeculae, partially enclosing many intercommunicating spaces filled with bone marrow. Consequently, due to their trabecular structure, cancellous bones are more amorphous than compact bones, and have many more channels with various blood cell precursors mixed with capillaries, venules and arterioles. Bipolar device 5i disclosed herein may be particularly useful to treat cancellous bone and to provide hemostasis and seal bleeding structures such as the above micro-vessels (i.e. capillaries, venules and arterioles) in addition to veins and arteries. Device 5i may be particularly useful for use during orthopedic knee, hip, shoulder and spine procedures (e.g. arthroplasty).

During a knee replacement procedure, the condyle at the distal epiphysis of the femur and the tibial plateau at the proximal epiphysis of the tibia are often cut and made more planer with saw devices to ultimately provide a more suitable support structure for the femoral condylar prosthesis and tibial prosthesis attached

thereto, respectively. The cutting of these long bones results in bleeding from the cancellous bone at each location. In order to seal and arrest the bleeding from the cancellous bone which has been exposed with the cutting of epiphysis of each long bone, bipolar device 5i may be utilized. Thereafter, the respective prostheses may
5 be attached.

Turning to a hip replacement procedure, the head and neck of the femur at the proximal epiphysis of the femur is removed, typically by cutting with a saw device, and the intertrochantic region of the femur is made more planer to provide a more suitable support structure for the femoral stem prosthesis subsequently
10 attached thereto. With respect to the hip, a ball reamer is often used to ream and enlarge the acetabulum of the innominate (hip) bone to accommodate the insertion of an acetabular cup prosthesis therein, which will provide the socket into which the head of the femoral stem prosthesis fits. The cutting of the femur and reaming of the hip bone results in bleeding from the cancellous bone at each location. In order to
15 seal and arrest the bleeding from the cancellous bone which has been cut and exposed, bipolar device 5i may be utilized. Thereafter, as with the knee replacement, the respective prostheses may be attached.

Bipolar device 5i may be utilized for treatment of connective tissues, such as for shrinking intervertebral discs during spine surgery. Intervertebral discs are
20 flexible pads of fibrocartilaginous tissue tightly fixed between the vertebrae of the spine. The discs comprise a flat, circular capsule roughly an inch in diameter and about 0.25 inch thick, made of a tough, fibrous outer membrane called the annulus fibrosus, surrounding an elastic core called the nucleus pulposus.

Under stress, it is possible for the nucleus pulposus to swell and herniate,
25 pushing through a weak spot in the annulus fibrosus membrane of the disc and into the spinal canal. Consequently, all or part of the nucleus pulposus material may protrude through the weak spot, causing pressure against surrounding nerves which results in pain and immobility.

Bipolar device 5i may be utilized to shrink protruding and herniated
30 intervertebral discs which, upon shrinking towards normal size, reduces the pressure on the surrounding nerves and relieves the pain and immobility. Device 5i may be applied via posterior spinal access under surgeon control for either focal shrinking of the annulus fibrosus membrane.

Where a intervertebral disc cannot be repaired and must be removed as part
35 of a discectomy, device 5i may be particularly useful to seal and arrest bleeding from the cancellous bone of opposing upper and lower vertebra surfaces (e.g. the cephalad surface of the vertebral body of a superior vertebra and the caudad surface of an inferior vertebra). Where the disc is removed from the front of the patient, for

example, as part of an anterior, thoracic spine procedure, device 5i may also be particularly useful to seal and arrest bleeding from segmental vessels over the vertebral body.

Bipolar device 5i may be utilized to seal and arrest bleeding of epidural veins which bleed as a result of the removal of tissue around the dural membrane during, for example a laminectomy or other neurosurgical surgery. The epidural veins may start bleeding when the dura is retracted off of them as part of a decompression. Also during a laminectomy, device 5i may be used to seal and arrest bleeding from the vertebral arch and, in particular the lamina of the vertebral arch.

As already discuss with respect to FIG. 6, even when general-purpose generator 6 is set to a predetermined "fixed" power output, the actual power delivered from generator 6 may be significantly different if the impedance is outside the range defined by of the generator's low and high impedance cut-off limits.

Also with respect to FIG. 6, the output power is identified as being set to 75 watts in the generator's bipolar mode of operation. With respect to general-purpose generators 6 currently used in the electrosurgical industry, it has been found that a significant portion of the generators only provide an output power of 50 watts in their bipolar mode, with only a few providing an output power of 70-75 watts in bipolar mode. Above 75 watts, a very small number of generators may provide power in their bipolar mode of 100 watts.

As is well known, the maximum output power of a general-purpose generator 6 in its bipolar mode of operation is lower than the maximum output power of the generator in its monopolar mode of operation. One reason for this is that the electrodes commonly associated with a bipolar device are generally in much closer in proximity as compared to the active and return electrodes of a monopolar device, thus reducing the need for greater power. Furthermore, with additional power, use of many prior art dry tip electrosurgical devices only leads to more tissue desiccation, electrode sticking, char formation and smoke generation, thus further obviating the need for additional power.

However, as established above, bipolar device 5i of the present invention inhibits such undesirable effects of tissue desiccation, electrode sticking, char formation and smoke generation, and thus do not suffer from the same drawbacks as prior art dry tip electrosurgical devices.

It has been found that bipolar device 5i is, in certain instances, able to use significantly greater power than the output power current general-purpose generators offer in their accorded bipolar modes. For example, bipolar device 5i may use greater power to treat bone in knee, hip, shoulder and spine surgeries where blood loss would traditionally be particularly high thus necessitating a blood transfusion.

General-purpose generators may offer significantly greater output power than 75 watts when set in their monopolar modes. For example, in monopolar "cut mode", the maximum power output of the generator is typically in the range of 300 watts. However, in monopolar cut mode the voltage and preferred impedance ranges are much greater than in bipolar mode. For example, with respect to impedance, an exemplary low impedance cut-off for a monopolar cut mode is about 5 200 ohms while an exemplary low impedance cut-off for bipolar mode is about 25-50 ohms.

In order to reduce monopolar voltage and impedance ranges to desirable levels for bipolar use, a transformer may be placed in series circuit configuration 10 between the electrodes of bipolar device 5i and the monopolar mode power output of the generator 6.

As shown in FIG. 41, without a transformer, cable 9 of bipolar device 5i may ordinarily comprise two insulated wires 21a, 21b connectable to generator 6 via two 15 banana (male) plug connectors 77a, 77b connecting directly to (female) plug receptacles 79a, 79b of the generator 6 (shown in FIG. 45). As shown in FIG. 41, the banana plug connectors 77a, 77b are each assembled with wires 21a, 21b within individual housings 129a, 129b which are not connected relative to one another and may be referred to as "loose leads". Consequently, in this embodiment, the banana 20 plug connectors 77a, 77b are independently movable relative to one another. An exemplary electrical configuration established between banana plug connectors 77a, 77b of device 5i and banana plug receptacle connectors 79a, 79b of generator 6 is further illustrated in FIG. 45. From the above, it should be understood that the use 25 of plug connectors and receptacle connectors, is merely exemplary, and that other types of mating connector configurations may be employed.

However, with the introduction of a transformer 310 to convert monopolar output power to voltage and impedance ranges associated with bipolar output power, preferably the wires 21a, 21b, plug connectors 77a, 77b and transformer 310 are all 30 assembled and provided in a single, common housing similar to housing 129 shown in FIG. 9, and better shown in FIG. 57. In contrast to the previous embodiment, in this embodiment the plug connectors are held in a fixed, predetermined position relative to one another. In this manner, the plug connectors can be tailored to fit only those generators 6 with receptacle connectors positioned to coincide or match up with the predetermined positions of the plug connectors.

35 To further illustrate the above, FIG. 46 illustrates an exemplary electrical configuration which may be associated between monopolar device 5a and generator 6. As shown in FIG. 46, in this embodiment the wiring within plug housing 129 of device 5a is configured such that hand switch 15a may be electrically coupled to the

“coagulation mode” hand switching circuitry of generator 6. More specifically, as shown hand switch 15a is electrically coupled to generator 6 upon the insertion of hand switch plug connector 77d of device 5a into hand switch receptacle connector 79d of generator 6.

5 In addition to plug connector 77d, plug housing 129 also contains power plug connector 77c which may be electrically coupled to the monopolar power receptacle connector 79c of generator 6. As shown, upon insertion of power plug connector 77c into power receptacle connector 79c, electrode 25 is now coupled to the power output of generator 6.

10 As shown, the finally connection of device 5a to generator 6 comprises ground pad receptacle connector 177 of ground pad 125 being inserted over ground pad plug connector 179 of generator 6.

15 Plug connectors 77c, 77d are provided in a single common housing 129 to better and more easily direct the plug connectors 77c, 77d to their predetermined targeted plug receptacle connectors 79c, 79d by virtue of being held in a fixed, predetermined position relative to one another by plug housing 129 such that they can only coincide with receptacle connectors 79c, 79d, respectively.

20 In other embodiments, as indicated by the dotted lines, the wiring within plug housing 129 of device 5a may be configured such that hand switch 15a is coupled to plug connector 77e and plug receptacle 79e, in which case hand switch 15a is now electrically coupled to the monopolar “cut mode” of generator 6 rather than the coagulation mode.

25 Now, with use of a bipolar device 5i, as shown in FIG. 47, housing 129 now includes transformer 310 and monopolar device 5a has been replaced with bipolar device 5i, now also including hand switch 15a. Furthermore, as shown, hand switch 15a is coupled to the monopolar cut mode of generator 6 by use of plug connector 77e and plug receptacle 79e. In other embodiments, the hand switch 15a may be eliminated as shown in FIG. 48 and foot switch 15 may be used alone.

30 The option between monopolar “coagulation mode” hand switching and monopolar “cut mode” hand switching is driven by a number of factors. However, an overriding consideration is often output power. In monopolar coagulation mode, the maximum output power of a general purpose generator is typically about 120 watts, while in monopolar cut mode the maximum output power of the same general purpose generator is typically about 300 watts. For use of the monopolar devices disclosed herein (e.g. 5a, 5c), 120 watts maximum output power associated with coagulation mode has been found to be generally sufficient, thus precluding the need for higher powers associated with cut mode. However, for the bipolar device 5i, when using power provided from the generator’s monopolar output, the higher

power associated with monopolar cut mode is generally more desirable than the lower power associated with monopolar coagulation mode.

In other embodiments, the transformer 310 may be provided as part of an in-line adaptor 312, as shown in FIGS. 44 and 49. In this embodiment, preferably the 5 adapter 312 includes its own receptacle connectors 314a, 314b on one side which are configured to receive plug connectors 77a, 77b of device 5i, and on the opposing side has its own plug connector 316c and ground pad receptacle connector 177 which are configured to connect to receptacle connector 79c and ground pad plug connector 179 of generator 6, respectively. To further illustrate the above, FIG. 49 10 illustrates an exemplary electrical configuration which may be associated between bipolar device 5i, adapter 312 and generator 6.

The adaptor 312 may also be configured to accommodate a bipolar device with a hand switch. Without adaptor 312, FIG. 50 shows an exemplary electrical configuration established between plug connectors 77a, 77b of device 5i and receptacle connectors 79a, 79b of generator 6. In addition, FIG. 50 shows hand 15 switch 15a coupled to the hand switching circuitry of generator 6. More specifically, as shown hand switch 15a is electrically coupled to generator 6 upon the insertion of bipolar hand switch plug connector 77f of device 5i into bipolar hand switch receptacle connector 79f of generator 6.

With adaptor 312, as shown in FIG. 51 and as with the earlier embodiment, 20 preferably the adaptor 312 includes its own receptacle connectors 314a, 314b on one side which are configured to receive plug connectors 77a, 77b of device 5i, and on the opposing side has its own plug connector 316c and ground pad receptacle connector 177 which are configured to connect to receptacle connector 79a and ground pad plug connector 179 of generator 6, respectively. Furthermore, adaptor 25 312 has its own bipolar hand switch receptacle connector 314f on one side configured to mate with the bipolar hand switch plug connector 77f of device 5i, and on the opposing side has its own monopolar hand switch plug connector 316e configured to connect to monopolar "cut mode" hand switch receptacle connector 30 79e of generator 6. Finally, in order to establish the remaining link between the hand switch circuitry and the monopolar power output, the adaptor 312 has a hand switch plug connector 314g configured to mate with hand switch receptacle connector 77g of device 5i.

As shown in FIG. 51, bipolar device 5i now includes four connectors (i.e. 35 77a, 77b, 77f, 77g) when adaptor 312 is used rather than just the three connectors (i.e. 77a, 77b, 77f) associated with FIG. 50. Connector 77g is added to provide a connection, when mated with connector 314g of adaptor 312, to plug connector 316c which bypasses transformer 310. This is required as the hand switch circuitry of

generator 6 typically utilizes direct current (DC) rather than the alternating current (AC) associated with the power circuitry. Consequently, since continuous DC will not cross between the primary coil 318 and secondary coil 320 of transformer 310, this fourth connection is required.

5 Turning to the specifics of transformer 310, preferably the transformer 310 comprises primary and secondary coils 318, 320 comprising #18 magnet wire wound on a toroidal shaped, magnetic core 322. More preferably the core 322 comprises a ferromagnetic core and even more preferably a ferrite core. Preferably the ferrite has an amplitude permeability in the range of 500μ to $5,000 \mu$ and more preferably of about $2,000 \mu$. More preferably, the ferrite comprises ferrite material no. 77. Preferably the core has a 1.4 inch outside diameter, a 0.9 inch inside diameter and a 0.5 inch thickness which is available from Coil Winding Specialists.

10 For a perfect transformer, that is, a transformer with a coefficient of coupling (k) equal to 1, the impedances can be described as follows:

$$15 \quad Z_p = Z_s(N_p/N_s)^2 \quad (8)$$

where:

20 Z_p = Impedance looking into the primary terminals from the power source;
 Z_s = Impedance of load connected to secondary;
 N_p = Number of turns (windings) for primary coil; and
 N_s = Number of turns (windings) for secondary coil

Based a primary impedance $Z_p = 200$ ohms and a secondary impedance of 25-50 ohms, the transformer 310 should be a step-down transformer with a turns ratio, N_p/N_s , in the range between and including about 3:1-2:1, respectively, and preferably about 2.5:1. This will result in power being provided to the tissue in monopolar mode at much lower impedances (i.e. 25-50 ohms) than typically required for use of the generator's monopolar mode (i.e. 200 ohms).

25 Turning to voltage, the high impedance cut-off for bipolar mode at 75 watts occurs at about 300 ohms, with the power remaining substantially unchanged between 25 ohms and 300 ohms. Thus, based on Ohm's law, for 75 watts ohms and 300 ohms, the voltage before power begins to drop in bipolar mode is about 150 RMS volts. This now becomes the targeted voltage from the monopolar mode with use of the transformer 310.

30 The high impedance cut-off for monopolar mode at 150 watts occurs at about 1000 ohms. At 150 watts and 1000 ohms, the voltage in monopolar mode is about 387 RMS volts. With the transformer above, secondary voltage may be described as follows:

$$V_s = V_p(N_s/N_p) \quad (8)$$

where:

- 5 V_s = Secondary voltage;
- V_p = Primary voltage;
- N_p = Number of turns (windings) for primary coil; and
- N_s = Number of turns (windings) for secondary coil

Based on a primary voltage of 387 RMS volts, and a turns ratio N_p/N_s of 2.5:1, the secondary voltage is 155 RMS volts, which is only slightly greater than 10 the targeted 150 RMS volts. With respect to the number of windings, in one embodiment preferably, the primary coil 318 comprises 40 windings while the secondary coil 320 comprises 16 windings resulting in the turns ratio of 2.5.

In yet another embodiment, as shown in FIGS. 52-56, electrosurgical device 5i may include a fluid flow control mechanism for turning fluid flow on and off to 15 the tissue treating portion of the device, such as a roller pinch clamp assembly. As best shown in FIGS. 54-56, device 5i includes a roller pinch clamp assembly 242 and, more specifically, an inclined ramp roller pinch clamp assembly (as opposed to a parallel acting clamp).

As best shown in FIGS. 54-55, the clamp assembly 242 includes a housing 20 provided by handles 20a, 20b, a roller wheel 244 having a wheel center axis 246 and a guide pin hub. As shown, the guide pin hub is provided by pair of opposing, 20 integrally formed, cylindrical trunnions 248a, 248b, but may also be provided by a separately formed pin. Trunnions 248a, 248b are contained within and move along a track 250 preferably provided and defined by opposing trunnion channels 252a, 25 252b formed between wheel upper guide surfaces 254a, 254b and wheel lower guide surfaces 256a, 256b extending longitudinally and parallel inward from the side wall portions of the handles 20a, 20b. As shown, wheel upper guide surfaces 254a, 254b are provided by a lip portion of the handles 20a, 20b which partially define aperture 258 through which roller wheel partially extends while wheel lower 30 guide surfaces 256a, 256b are provided by ribs 260a, 260b.

Handles 20a, 20b also preferably provide tubing guide surfaces 272a, 272b which at least a portion of which provide a clamping surface against which plastic tubing 4b is clamped by roller 244. As best shown in FIGS. 54-55, tubing guide surfaces 272a, 272b are provided by ribs 270a, 270b. In use, fluid line 4b is 35 externally squeezed and compressed between the outer perimeter surface 262 of roller wheel 244 and at least a portion of tubing guide surfaces 272a, 272b. In this embodiment, preferably surface 262 is serrated.

Trunnions 248a, 248b support the movement of roller wheel 244 in two opposing directions, here proximally and distally, along track 250. As best shown in FIGS. 55-56, the separation distance between the outer perimeter surface 262 of roller wheel 244 and tubing guide surfaces 272a, 272b changes throughout the proximal and distal travel of roller wheel 244 along track 250. More specifically, the separation distance between the outer perimeter surface 262 of roller wheel 244 and tubing guide surfaces 272a, 272b is greater between the outer perimeter surface 262 of roller wheel 244 and distal end portions 274a, 274b of tubing guide surfaces 272a, 272b provided by distal end portions 264a, 264b of ribs 270a, 270b than between the outer perimeter surface 262 of roller wheel 244 and proximal end portions 276a, 276b of tubing guide surfaces 272a, 272b provided by proximal end portions 266a, 266b of ribs 270a, 270b.

As shown in FIGS. 54-55, when axis 246 of roller wheel 244 is opposing distal end portions 274a, 274b of tubing guide surfaces 272a, 272b, preferably the separation distance is configured such that the tubing 4b may be uncompressed and the lumen of tubing 4b completely open for full flow therethrough. Conversely, as shown in FIG. 56, when axis 246 of roller wheel 244 is opposing proximal end portions 276a, 276b of tubing guide surfaces 272a, 272b preferably the separation distance is configured such that the tubing 4b is compressed and the lumen of tubing 4b is completely blocked so that the flow of fluid through tubing 4b is prevented.

Distal end portions 274a, 274b of tubing guide surfaces 272a, 272b are separated from proximal end portions 276a, 276b of tubing guide surfaces 272a, 272b by transition surfaces 278a, 278b which are provided by transition rib portion 268a, 268b of ribs 270a, 270b. Preferably compression of tubing initially begins between transition surfaces 278a, 278b and the outer perimeter surface 262 of roller wheel 244 and increases as wheel 244 moves proximally along proximal end portions 276a, 276b of tubing guide surfaces 272a, 272b. With this configuration, consideration may be given to eliminating at least that portion of distal end portions 274a, 274b of tubing guide surfaces 272a, 272b that do not contribute to compression of the tubing 4b. However, given that of distal end portions 274a, 274b of tubing guide surfaces 272a, 272b guide tubing 4b to splitter 240, such may not be desirable.

As shown in FIGS. 54-56, both transition surfaces 278a, 278b and proximal end portions 276a, 276b of tubing guide surfaces 272a, 272b provide sloped inclining surfaces proximally along their respective lengths which decreases the separation distance between the outer perimeter surface 262 of roller wheel 244 and the tubing guide surfaces 272a, 272b as the wheel 244 moves proximally. As shown, preferably the transition surfaces 278a, 278b and proximal end portions

276a, 276b of tubing guide surfaces 272a, 272b have different slopes such that the separation distance decreases at a faster rate along transition surfaces 278a, 278b as compared to proximal end portions 276a, 276b of tubing guide surfaces 272a, 272b. In this manner, compression of tubing 4b is non-linear along the length of travel of 5 wheel 244 with a majority of the compression occurring between roller wheel 244 and transition surfaces 278a, 278b. More preferably, the lumen of tubing 4b is completely blocked when roller wheel 244 is compressing the tubing 4b against the proximal portion of transition surfaces 278a, 278b, and the added compression of the tubing 4b along proximal end portions 276a, 276b of tubing guide surfaces 10 272a, 272b provides an additional safety to assure complete blocking of the lumen even where there are variations in the tubing, such as the size of the lumen.

It should be realized that, due to the slope of the transition rib portion 268a, 268b, as the roller wheel 244 moves proximally relative to transition surfaces 278a, 278b the lumen of tubing 4b is blocked incrementally. Thus, in addition to 15 providing an on/off mechanism, the roller pinch clamp assembly 242 can also be used to regulate the fluid flow rate between two non-zero flow values. It should also be realized that the roller pinch clamp assembly 242 of the device may be used in series conjunction with another roller pinch clamp assembly which is typically provided as part of an IV set (i.e. IV bag, IV bag spike, drip chamber, connecting 20 tubing, roller clamp, slide clamp, luer connector). When used in this manner, the roller pinch clamp assembly of the IV set may be used to achieve a primary (major) adjustment for fluid flow rate, while the roller pinch clamp assembly 242 of the device may be used to achieve a secondary (more precise minor) adjustment for the fluid flow rate.

25 In another embodiment, as shown in FIGS. 57-59 for device 5i, roller wheel 244 of roller pinch clamp assembly 242 may be concealed from view to reduce the possibility of foreign objects (e.g. practitioner's rubber gloves) from entering into the confines of handle 20a, 20b through aperture 258 and getting snagged, for example, between the trunnions 248a, 248b and track 250.

30 As shown in FIG. 57, roller wheel 244 is concealed from view by handle portions 20a, 20b. As shown, switch button 192 protrudes through an aperture 194 formed in handle portions 20a, 20b. Button 192 is preferably integrally connected via a single piece polymer molding to a proximally extending switch arm 196 which provides a receptacle 306 which contains and holds roller wheel 244.

35 With use of the fluid flow control mechanism of FIGS. 57-59, in response to button 192 being moved proximally and distally in switch button aperture 194, switch arm 196 moves proximally and distally along track 250, which correspondingly moves roller wheel 244 to compress tubing 4b as discussed above.

As best shown in FIG. 59, preferably the fluid flow control mechanism further comprises a mechanism which may hold the arm 196 in a fixed position while compressing and occluding fluid line 4b. As shown, preferably the locking mechanism comprises detents 308a, 308b (308b not shown) formed in handle portions 20a, 20b which partially receive trunnions 248a, 248b therein to hold arm 196 in a fixed position.

The devices of the present invention may provide treatment of tissue without using a temperature sensor built into the device or a custom special-purpose generator. In a preferred embodiment, there is no built-in temperature sensor or other type of tissue sensor, nor is there any custom generator. Preferably, the invention provides a means for controlling the flow rate to the device such that the device and flow rate controller can be used with a wide variety of general-purpose generators. Any general-purpose generator is useable in connection with the fluid delivery system and flow rate controller to provide the desired power; the flow rate controller will accept the power and constantly adjust the saline flow rate according to the control strategy. Preferably, the generator is not actively controlled by the invention, so that standard generators are useable according to the invention. Preferably, there is no active feedback from the device and the control of the saline flow rate is "open loop." Thus, in this embodiment, the control of saline flow rate is not dependent on feedback, but rather the measurement of the RF power going out to the device.

The use of the disclosed devices can result in significantly lower blood loss during surgical procedures such as liver resections. Typical blood loss for a right hepatectomy can be in the range of 500 – 1,000 cubic centimeters. Use of the devices disclosed herein to perform pre-transection coagulation of the liver can result in blood loss in the range of 50 – 300 cubic centimeters. Such a reduction in blood loss can reduce or eliminate the need for blood transfusions, and thus the cost and negative clinical consequences associated with blood transfusions, such as prolonged hospitalization and a greater likelihood of cancer recurrence. Use of the device can also provide improved sealing of bile ducts, and reduce the incidence of post-operative bile leakage, which is considered a major surgical complication.

For purposes of the appended claims, the term "tissue" includes, but is not limited to, organs (e.g. liver, lung, spleen, gallbladder), highly vascular tissues (e.g. liver, spleen), soft and hard tissues (connective, bone, cancellous) and tissue masses (e.g. tumors).

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications can be made therein without departing from the spirit of the invention and the scope of the

appended claims. The scope of the invention should, therefore, be determined not with reference to the above description, but instead should be determined with reference to the appended claims along with their full scope of equivalents. Furthermore, it should be understood that the appended claims do not necessarily 5 comprise the broadest scope of the invention which the Applicant is entitled to claim, or the only manner(s) in which the invention may be claimed, or that all recited features are necessary.

All publications and patent documents cited in this application are incorporated by reference in their entirety for all purposes.